**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF NEW YORK**

| | |
|---|---|
| IN RE SPERO THERAPEUTICS, INC. SECURITIES LITIGATION | Civil No. 1:22-cv-03125-LDH-RLM<br><br>CLASS ACTION |
| THIS DOCUMENT RELATES TO:<br>All Actions | FIRST AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS |

# TABLE OF CONTENTS


I. NATURE OF THE ACTION ....1
II. JURISDICTION AND VENUE ....5
III. PARTIES ....6
IV. NON-PARTY CONFIDENTIAL WITNESSES ....7
V. SUBSTANTIVE ALLEGATIONS ....9
A. Treatment Of Complicated Urinary Tract Infections (cUTI) ....9
B. Spero's Business & Operations ....11
C. The Market Closely Watched Spero's Progress Toward FDA Approval ....12
D. Undisclosed, Material, Negative Facts ....18
1. *Undisclosed Facts And Risks Described By The CWs* ....18
2. *Undisclosed Facts And Risks Belatedly Admitted By Defendants* ....23
E. Materially False and Misleading Statements & Omissions ....25
1. *Business Operations & Clinical Trial Fraud* ....25
2. *Reported Results Fraud* ....104
3. *Internal Controls Fraud* ....116
4. *Partial Corrective Disclosures Incrementally Revealed The Frauds* ....121
F. Additional Facts Probative of Scienter ....125
1. *Defendants' Knowledge Or Reckless Disregard Of Red Flags* ....125
2. *Defendant Mahadevia Was Financially Motivated To Commit Fraud* ....130
3. *The Individual Defendants Reaped Suspicious Compensation* ....133
4. *Spero Raised Funds During The Class Period* ....134
5. *Spero Reaped Unearned Windfall Government Payments* ....135
6. *The Fraud Implicated Core Operations* ....136
7. *The Individual Defendants Signed, Were Quoted In, Or SOX-Certified The Alleged Misstatements* ....136
8. *The Fraud Violated Spero's Corporate Code of Conduct* ....137
VI. NO SAFE HARBOR ....139
VII. THE CLAIMS ARE TIMELY ....141
VIII. LOSS CAUSATION/ECONOMIC LOSS ....142

IX. PRESUMPTION OF RELIANCE ..... 143
X. PLAINTIFFS' CLASS ACTION ALLEGATIONS ..... 144
XI. CLAIMS FOR RELIEF ..... 147
COUNT I ..... 147
COUNT II ..... 151
XII. PRAYER FOR RELIEF ..... 152
XIII. DEMAND FOR TRIAL BY JURY ..... 152

1. Lead Plaintiff Kashif Memon, along with additional plaintiffs Richard S. Germond and Nabil Saad (altogether "Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their complaint against Defendants, allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys, which included a review of Defendants' public statements and publicly available documents, conference calls, presentations, announcements, Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Spero Therapeutics, Inc. ("Spero"), analysts' reports and advisories and other press coverage about Spero, Spero's stock chart, Spero's corporate website, data obtained through news services such as Bloomberg and Yahoo! Finance, interviews with certain confidential witnesses ("CWs") who were former employees of Spero, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## I. NATURE OF THE ACTION

2. This is a class action for violations of the federal securities laws brought by Lead Plaintiff Kashif Memon, and additional Plaintiffs Richard S. Germond and Nabil Saad (together, "Plaintiffs"), individually and on behalf of all persons who purchased or otherwise acquired Spero Therapeutics ("Spero") common stock between September 8, 2020, and May 3, 2022, inclusive (the "Class Period"). Plaintiffs allege violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b¬5 promulgated thereunder by the Securities and Exchange Commission ("SEC") (17 C.F.R. § 240.10b-5), against Defendants Spero, Ankit Mahadevia (Spero's CEO), and Satyavrat Shukla (its CFO).

3. Spero is a pharmaceutical company that during the Class Period had a primary drug candidate, SPR994, a/k/a tebipenem pivoxil hydrobromide ("tebipenem HBr"), for which it sought FDA approval as an anti-bacterial treatment in pill form that could treat serve as an alternative urinary tract infection treatment as an alternative to a widely used, FDA-approved intravenous drug called ertapenem. Before the Class Period, Defendants launched a Phase 3 clinical trial, called the ADAPT-PO Trial, to generate the data necessary to support a New Drug Application (NDA) for tebipenem HBr. Relevant to this action, the ADAPT-PO Trial had to demonstrate that tebipenem HBr had a non-inferiority margin of -12.5% when compared against IV ertapenem.

4. The Class Period begins with the Defendants pounding a steady drumbeat of statements like this one on September 8, 2020: "***The pivotal Phase 3 clinical trial of oral tebipenem HBr met the primary endpoint, demonstrating statistical non-inferiority versus IV ertapenem.***" They also said that "***Results were similar between treatment arms across all subgroups of patients***" and that the ADAPT-PO Trial could serve the "***One well-controlled pivotal trial to form the basis for an NDA submission***." The same month, they proclaimed that "***oral tebipenem is comparable in its effectiveness for cUTI patients to IV ertapenem meeting the minus 12.5 percent non-inferiority margin set up by the FDA***." By October 2020, they were saying that tebipenem HBr "***is a carbapenem with broad-spectrum activity against Gram-positive and -negative bacteria that is being developed for the treatment of patients with complicated urinary tract infections***." Statements like these pervade the Class Period.

5. Significantly, Defendants worked extremely closely with the FDA as they sought to use the ADAPT-PO Trial results to support tebipenem HBr's NDA submission and to seek FDA approval. Well before the Class Period, the FDA granted tebipenem HBr a Fast Track Designation, which facilitates development and expedites review of certain high-value drug candidates. As a

result, ***Defendants were given the ability to interact more frequently with the FDA*** regarding tebipenem HBr's development ***their NDA submission was subject to a rolling review by the FDA***. Thus, Defendants enjoyed atypical access to the FDA that permitted them to discuss the sufficiency of the ADAPT-PO Trial's evaluable patient population and its ability to meet the non-inferiority margin and to receive the FDA's feedback on these issues.

6. At the start of the Class Period Defendant Mahadevia publicly discussed the upcoming "***pre-NDA meetings***" (plural) with the FDA. By March 2021, Defendants publicly disclosed that ***at least one pre-NDA meeting had occurred*** and, they expressly stated, under analyst questioning, that they had ***discussed*** "***the format and content of the planned data package***" that would support the tebipenem HBr NDA and said that they had "***received feedback***" from the FDA. By September 20221, Defendant Mahadevia publicly referenced not only the pre-NDA meeting from March 2021, but also "***multiple***" ***antecedent*** discussions with the FDA that concerned whether the ADAPT-PO Trial could support the NDA submission for tebipenem HBr. Confidential witnesses (CWs), former employees of Spero, describe a fever pitch of interactions during December 2021, January 2022, and February 2022, with the FDA asking an unusually high amount of questions regarding the clinical data as often as "a couple of times a week."

7. Meanwhile, the Defendants reaped financial windfalls. Defendant Mahadevia generated suspiciously high net gains from insider transactions. Defendants Mahadevia and Shukla both were given suspiciously high executive compensation enhancements. Spero raised nearly $86 million from a stock offering, and it reaped millions of dollars in payments under a U.S. government contract meant to spur the advancement of important public health therapies. At the same time, Defendants reported positive operating and financial metrics, which they certified

under the Sarbanes-Oxley Act of 2002 (a/k/a SOX), without disclosing making appropriate disclosure of negative underlying risks or trends.

8. Thus, analysts and investors – like the CWs – were shocked when Spero issued an after-hours prese release on March 31, 2022, abruptly announced that "***[t]he U.S. Food and Drug Administration (FDA) has notified Spero that, as part of its ongoing review of Spero's New Drug Application (NDA) for tebipenem HBr, it has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time***." On this news, Spero's stock price fell $1.59 per share, or 18.28%, on exceptionally high volume, from a close of $8.70 per share on March 31, 2022, to close at $7.11 per share on April 1, 2022.

9. Defendants sought to mute the effects of this disclosure, by publicly and internally expressing confidence that the company could remedy the deficiencies in the leadup to a Late Cycle Meeting (LCM) with the FDA in late April 2022. However, internally, Defendants refused to disclose to employees the nature of the FDA's concerns or the deficiencies with the ADAPT-PO Trial and severely restricted access to the company's servers housing the trial data to a very tight circle of individuals. Analysts, investors, and employees remained cautiously optimistic.

10. All were once again stunned when on May 3, 2022 Spero issued another press release announcing "that it ***will immediately defer current commercialization activities for tebipenem HBr based on feedback from a recent Late Cycle Meeting (LCM) with the U.S. Food and Drug Administration (FDA) regarding Spero's New Drug Application (NDA) for tebipenem HBr***[,]" and that, "[a]lthough the review is still ongoing and the FDA has not yet made any final determination regarding approvability, the ***discussion suggested that the data package may be insufficient to support approval during this review cycle***." The press release explained that te FDA had reduced the number of evaluable patients in the ADAPT-PO Trial data set, by removing

the gram-positive patients, with the result that "***the pre-specified non-inferiority (NI) margin of -12.5% was not met.***" It added, "In connection with this development, ***Spero announced that it is undertaking a reduction in its workforce by approximately 75% and a restructuring of its operations to reduce operating costs and reallocate resources***." Just five days after the LCM, 75% of the company's workforce were abruptly terminated with severance payments transmitted. The CWs expressed astonishment at the pacing of these moves, which had to have been planned for quite some time. On this news, Spero's stock price sharply declined an additional $3.24 per share, or 63.65%, on massive volume, from a close of $5.09 per share on May 2, 2022, to close at $1.85 per share on May 3, 2022.

11. As a result of Defendants' wrongful acts and omissions as alleged herein, and the precipitous decline in the market value of Spero's securities, Plaintiffs and the other Class members have suffered huge losses and damages, for which this action seeks recovery.

## II. JURISDICTION AND VENUE

12. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

14. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b) as the alleged misstatements entered and subsequent damages took place in this Judicial District. Pursuant to Spero's most recently filed Quarterly Report with the SEC, as of November 10, 2022, there were 51,776,053 shares of Spero's common stock outstanding. Spero's securities trade on the Nasdaq Global Select Market ("NASDAQ").

Accordingly, there are presumably hundreds, if not thousands, of investors in Spero securities located within the U.S., some of whom undoubtedly reside in this Judicial District.

15. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

## III. PARTIES

16. Lead Plaintiff Kashif Memon, as set forth in the attached Certification, which is incorporated by reference herein, purchased Spero's U.S.-traded stock at artificially inflated prices during the Class Period and was damaged upon the revelation of Defendants' fraud, as alleged herein.

17. Plaintiff Richard S. Germond, as set forth in the attached Certification, which is incorporated by reference herein, purchased Spero's U.S.-traded stock at artificially inflated prices during the Class Period and was damaged upon the revelation of Defendants' fraud, as alleged herein.

18. Plaintiff Nabil Saad, as set forth in the attached Certification, which is incorporated by reference herein, purchased Spero's U.S.-traded stock at artificially inflated prices during the Class Period and was damaged upon the revelation of Defendants' fraud, as alleged herein.

19. Defendant Spero is a Delaware corporation with principal executive offices located at 675 Massachusetts Avenue, 14th Floor, Cambridge, Massachusetts 02139. Spero's securities trades on the NASDAQ under the symbol "SPRO."

20. Defendant Ankit Mahadevia ("Mahadevia") has served as Spero's Chief Executive Officer ("CEO") and as a board member at all relevant times.

21. Defendant Satyavrat Shukla ("Shukla") served as Spero's Chief Financial Officer ("CFO") from January 4, 2021 to the present.

22. Defendants Mahadevia and Shukla are sometimes collectively referred to herein as the "Individual Defendants." The Individual Defendants, throughout the Class Period, because of their positions with Spero, possessed the power and authority to control the contents of Spero's SEC filings, press releases and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant, while serving as a senior executive of Spero, was provided with copies of Spero's SEC filings and press releases alleged herein to have been false or misleading prior to, or shortly after, their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public, and that the positive representations which were being made were then materially false and/or misleading.

23. Defendant Spero and the Individual Defendants are referred to herein, collectively, as the "Defendants."

## IV. NON-PARTY CONFIDENTIAL WITNESSES

24. Below are the descriptions of the Confidential Witnesses whose statements are among the factual bases for this pleading.

25. CW1 was the Director of Clinical Data Management at Spero from February 2019 to February 2022. CW1 initially reported to VP and Head of Clinical Operations Susannah Walpole and, after Ms. Walpole was replaced by new Head of Clinical Operations Sheila Wilson in January 2021, CW1 reported to Ms. Wilson. CW1 was in charge of data management for the tebipenem HBr clinical trial that was submitted to the FDA as part of the company's NDA. CW1

oversaw creation of the database for the trial, which was done by a third party. CW1 also was responsible for overseeing data collection from the trial sites, ensuring the data was legible, verifiable, and contemporaneous – essentially ensuring that when the data went to the statisticians, it was clean and had "no holes."

26. CW2 was an Associate Director in the Regulatory Affairs Department at Spero from July 2021 to May 2022. CW2 reported to Spero VP of Regulatory Affairs Jennifer Liscouski. With 20 years of experience, CW2 was hired to assist with the tebipenem HBr NDA submission to the FDA. CW2 worked as an operational part of the regulatory affairs department and was responsible for gathering data and documents that would be part of the NDA submission. Once the NDA was submitted, CW2 worked to help Spero respond to inquiries and requests from the FDA as the NDA moved through the review process.

27. CW3 was a Lead Medical Science Liaison Director at Spero from May 2021 to May 2022, when CW3 was laid off. CW3 had direct-line reporting to the Spero C-suite. CW3 reported to Spero Executive Director of Field Medical Affairs Lisa Dipompo, who in turn reported to Spero Chief Operating Officer Christina Larkin ("Larkin") and Spero SVP of Medical Affairs Jennifer Reece. CW3 spoke with health care professionals in the field about cUTI and treatment, and CW3 answered their questions about tebipenem HBr based on CW3's knowledge of the clinical trials.

28. CW4 was a Medical Science Liaison at Spero from October 2021 to April 2022, when CW4 was laid off. Like CW3, CW4 had direct-line reporting to Spero COO Larkin by reporting to Ms. Dipompo, who in turn reported to Larkin. CW4 spoke with physicians who would potentially use tebipenem HBr to discuss its scientific components and published clinical studies.

29. CW5 worked as a high-level employee in Spero's commercial division from 2018 to May 2022, reporting directly to Spero COO Larkin. CW5 was responsible for preparing marketing material for the potential launch of tebipenem HBr. CW5 gathered information from doctors and others in the medical community about their opinions concerning tebipenem HBr and the ADAPT-PO Trial's results. CW5 also assisted Spero in its preparations for the Late Cycle Meeting (LCM) with FDA, which took place on April 28 or 29, 2022.

30. CW6 was a Medical Science Liaison at Spero from January 2021 to May 2022. CW6 reported to Ms. DiPompo. As a Medical Science Liaison, CW6 educated the medical community and answered their questions about tebipenem HBr clinical trials and the disease state, cUTIs, that could potentially be treated by tebipenem HBr if approved.

## V. SUBSTANTIVE ALLEGATIONS

### A. Treatment Of Complicated Urinary Tract Infections (cUTI)

31. The majority of urinary tract infection ("UTI") pathogens are known as gram-negative pathogens. These include pathogens known as Enterobacterales, with Escherichia coli (E. coli) being the most common. A small percentage (about 10%) of UTI pathogens are gram-positive. These include pathogens such as Enterococci, of which Enterococcus Faecalis is the most common species. Some Enterobacterales pathogens that are particularly resistant to antibiotics include expended-spectrum ß-lactamase positive (ESBL+), fluoroquinolone-nonsusceptible (FQ-NS), and trimethoprim-sulfamethoxazole-resistant (TMP-SMX-R).

32. A UTI is classified as complicated ("cUTI") when a patient presents with any functional, metabolic, or anatomical condition that may increase the risk of treatment failure or adverse outcomes. Given their rarity and difficulty to treat, all UTIs that occur in men and children are often classified as complicated. Conditions and risk factors in women that contribute to a UTI to be classified as complicated include, but are not limited to age, pregnancy, cancer, diabetes,

bladder obstruction, and a weakened immune system. Even if a condition or risk factor is not present, a UTI may still be classified as complicated if it does not respond to first-level oral antibiotics. Untreated UTIs can lead to serious complications that require emergency medical care and may be life-threatening.

33. Carbapenems are decades-old antibiotics that are frequently used to treat many multi-drug resistant bacterial ("MDR") infections, which are resistant to first-line options, because they are safe and effective. They are largely effective because they possess the broadest spectrum of activity and greatest potency against gram-positive and gram-negative bacteria. Carbapenems, which were formerly viewed as a drug of last resort used to treat patients who become severely ill, have become increasingly utilized and are viewed as a "gold standard" treatment for certain suspected MDR infections. To date, U.S.-approved carbapenems are only available to be administered intravenously, which requires hospitalization.

34. IV ertapenem, an IV administered carbapenem, is currently the approved drug that is used to treat cUTIs that are resistant to first-level oral antibiotics available for treatment. Given the burden of hospitalization and associated costs, providers generally try to restrict the use of IV ertapenem and other IV administered carbapenems. The development of an orally administered treatment would be significant as it can prevent hospitalization or accelerate patient discharge and provide a cost-efficient alternative to IV treatment. With COVID-19 a very serious risk throughout the Class Period until today, being able to keep patients out of the hospital has become even more important. Further, bringing an orally administered treatment to market is highly desirable and offers a lucrative opportunity for pharmaceutical companies to acquire significant market share since there are none currently available on the market.

**B. Spero's Business & Operations**

35. Founded in 2013 and headquartered in Cambridge, Massachusetts, Spero (NASDAQ: SPRO) is a clinical-stage biopharmaceutical company that focuses on identifying, developing, and commercializing treatments for MDR bacterial infections and rare diseases in the US. Entering the Class Period, Spero had three primary product candidates. Two of its early-stage product candidates were SPR206, a direct acting IV-administered agent to treat MDR gram-negative bacterial infections in the hospital, and SPR720, an oral antibiotic for the treatment of non-tuberculous mycobacterial pulmonary disease. The most advanced of its product candidates entering the Class Period was SPR994, a/k/a tebipenem HBr (tebipenem pivoxil hydrobromide), which Spero frequently described as its "lead product candidate." Spero also has several licensing agreements to support the development of its product candidates, including the one with Meiji to support the development of tebipenem HBr, as discussed *infra*.

36. Tebipenem is a carbapenem antimicrobial. Tebipenem pivoxil is the orally bioavailable prodrug of tebipenem that protects the active drug from being cleaved in the stomach acid. Tebipenem pivoxil was developed by Meiji Seika Pharma Co. Ltd. ("Meiji"), licensed to Spero, and has been marketed in Japan since 2009 as Orapenem, a treatment in granule form for common pediatric infections. The subject of the ADAPT-PO Trial (defined *infra*) was tebipenem pivoxil hydrobromide ("tebipenem HBr")[1], which is the orally bioavailable carbapenem prodrug (tebipenem pivoxil) packed into a pill with HBr salt. Spero designed tebipenem HBr to enable high dosage and a room-temperature-stable product. Tebipenem HBr sought to become the first broad spectrum oral carbapenem-class antibiotic treating MDR gram-negative infections, including cUTI

[1] Many references in the complaint to the ADAPT-PO Trial drug are to tebipenem HBr and use this term; however, as will be seen *infra*, some references use the shorthand of "tebipenem" to refer to the tebipenem HBr formulation.

and acute pyelonephritis ("AP") in the US. If approved, tebipenem HBr would have offered a less burdensome alternative to traditional IV administered carbapenems which may prevent hospitalizations, accelerate patient discharge, and offer more convenient and cost-effective patient treatment after hospitalization.

37. Spero's development of an oral carbapenem (tebipenem HBr) to treat cUTIs, AP, and other MDR infections was viewed by several analysts as de-risked, given that the safety and tolerability of tebipenem pivoxil was earlier established in Japan through real-world safety data. Meiji conducted two exploratory Phase 2 clinical trials in Japan which revealed tebipenem was highly effective in the treatment of cUTIs.

38. Approaching the Class Period, developing and bringing tebipenem HBr to market was significant to Spero's viability and the performance of its stock. Tebipenem HBr, as Spero's most advanced product candidate, represented its most immediate source of revenue – a particularly significant fact, given that Spero has no marketed products and only two other early-stage product candidates in its pipeline. The lack of diversity in its portfolio made Spero heavily reliant upon obtaining FDA approval of tebipenem HBr and bringing it to market.

### C. The Market Closely Watched Spero's Progress Toward FDA Approval

39. Spero announced the initiation of a Phase 1 safety, tolerability, and pharmacokinetics study of tebipenem HBr on October 20, 2017. In its announcement, Spero outlined plans for a "rapid development approach with [tebipenem HBr]" that supported rapid initiation of a single pivotal Phase 3 trial contingent upon successful results of the Phase 1 study. Spero also revealed that the FDA recently designated tebipenem HBr as a Qualified Infectious Disease Product ("QIDP") for cUTIs. This designation incentivizes manufactures of new antibiotic treatments by offering them benefits including FDA priority review and eligibility for additional market exclusivity.

40. Three days after announcing the Phase 1 study and its intention to rapidly develop tebipenem HBr in an effort to expedite it to market, Spero launched its IPO, which it completed on November 6, 2017, raising approximately $83.6 million in gross proceeds. Spero continued to emphasize its rapid development plan for tebipenem HBr, including its plan for imminent initiation of a Phase 3 clinical trial.

41. Spero initiated U.S. patient enrollment into the "pivotal" global Phase 3 clinical trial (the "ADAPT-PO Trial") on February 4, 2019, when the FDA accepted its Investigational New Drug ("IND") application for tebipenem HBr. The IND application acceptance permitted Spero to transport tebipenem HBr across state lines to clinical investigators for testing. On March 29, 2019, Spero announced that tebipenem HBr was granted Fast Track Designation by the FDA, which facilitates development and expedites review of drugs intended to treat serious or life-threating conditions that demonstrate the potential to address unmet medical needs. As part of receiving fast track designation, Spero obtained ***the ability to interact more frequently with the FDA regarding the development of tebipenem HBr*** and the ***opportunity for rolling review of its New Drug Application (NDA)***. Relevant pharmacokinetic data was expected in the second half of 2019, and by October 3, 2019, the first 70 patients were enrolled.

42. Spero continued to express optimism about its ADAPT-PO Trial after completing total enrollment of 1,372 patients by May 2020. When announcing its Q2 2020 operating results in an earnings release on August 6, 2020, Spero stated its expectation of reporting top-line data from the ADAPT-PO Trial in Q3 2020.

43. On September 8, 2020, Spero reported the ADAPT-PO Trial top-line data in a press release touting its "positive" results, indicating that tebipenem HBr was well tolerated, had a similar safety profile as ertapenem, and, significantly, met the necessary threshold of a -12.5%

non-inferiority ("NI") margin as compared against the already-approved IV drug, IV ertapenem. Thus, as the Class Period began, the market was led to believe that the prospect of obtaining FDA approval for tebipenem HBr was strong based on positive ADAPT-PO Trial data.

44. Analysts covering Spero keenly followed every step of tebipenem HBr's development, emphasizing its utmost significance to Spero's viability:

(a) After Spero's IPO in November 2017, analysts initiated coverage of Spero and SPR994 very positively, with an expectation that a Phase 3 cUTI study would be complete in 2020 and FDA approval for cUTI and launch would occur in 2021. For example, in its November 27, 2017 analyst report, Oppenheimer initiated its coverage with an Outperform rating stating that SPR994 is a "unique oral carbapenem option that could accelerate hospital discharge, reduce total cost of treatment and decrease reinfection rates" and "[w]ith a pivotal Ph3 cUTI study expected to complete in 2020 and an expedited regulatory review, we expect SPR994 to receive FDA approval for complicated urinary tract infections (cUTI) and launch in 2021." Additionally, in its November 27, 2017 analyst report, Cowen stated that it saw an "excellent chance of success for the planned Ph3 of lead drug SPR994 in cUTI" and viewed the "safety dataset as a differentiating factor for [SPR994], as many antibiotic candidates fail in the clinic due to human safety."

(b) Just prior to top-line results from the Phase 1 SPR994 study, analysts particularly were encouraged about SPR994's differentiation. For example, in its January 11, 2018 analyst report, Oppenheimer stated, "[w]e see SPR994 as clearly differentiated and relatively de-risked with a significant commercial opportunity based on previous examples of oral antibiotics." In its February 8, 2018 analyst report, Cantor Fitzgerald initiated its coverage of Spero stating, "[w]e think SPR994's broad-spectrum activity against multi-drug resistant (MDR) Gram-negative bacteria has demonstrated potency comparable to that of IV-administered agents, supporting

SPR994's oral viability" and that it could obtain a "solid share" of the market. In its May 13, 2018 analyst report, Oppenheimer noted that investors, too, viewed SPR994 very positively and had high expectations for its advancement toward receiving FDA approval stating that "[i]nvestors we speak to are impressed with de-risking and differentiation provided by Japanese SPR994 data, supporting safety and efficacy which leads to a facilitated regulatory pathway in cUTI."

(c) Analysts continued to react favorably to SPR994's progress when Spero announced its expectation that incoming positive Phase 1 trial data would support advancement straight to a Phase 3 trial. For example, in its July 9, 2018 analyst report, Cantor Fitzgerald stated "[w]e think this is very good news for SPRO and underscores a unique investment opportunity with a strong value proposition because: (1) [Spero] is moving directly from Phase 1 to Phase 3; 2) [Single Ascending Dose] SAD data demonstrates [Spero] has an IV in a pill; And, 3) SPR994 could be the first oral carbapenem in the U.S. for cUTI patients that can and want to avoid hospitalization." Several other analyst reports reacted favorably to the news and viewed it as being in line with Spero's previous guidance.

(d) News that Spero was awarded a contract for SPR994 from the U.S. Biomedical Advanced Research and Development Authority ("BARDA"), which is part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, amounting to $15.7M, with the potential to reach up to $28.5M in additional funds over 5 years, led to continued optimism among analysts. In in its July 16, 2018 analyst report, Oppenheimer stated, "[W]e see today's BARDA partnership as an important source of non-dilutive funding, providing $15.7+$1.25M upfront with the potential of reaching $54.2M in total funds." Cantor Fitzgerald, in its July 17, 2018 analyst report, also asserted that "[t]his news is a strong endorsement of the clinical potential for SPR994."

(e) Analysts also reacted favorably to Spero's reported positive results from a final analysis of its Phase 1 clinical trial of SPR994. Cantor Fitzgerald viewed the positive results as "good news" in its September 27, 2018 analyst report. Cowen described the data as "extremely encouraging" in its November 11, 2018 analyst report. Oppenheimer stated, in its September 30, 2018 analyst report, that the "study should set the stage for a potentially paradigm-shattering transformation from IV standard of care to oral SPR994 that would result in substantial benefits to patients, physicians and payers."

(f) Analysts remained encouraged after Spero announced that the FDA accepted their IND application for SPR994, keeping Spero on track to initiate its planned single pivotal Phase 3 trial. For example, in its February 4, 2019 analyst report, Cantor Fitzgerald stated that "[w]e continue to believe the market opportunity for SPR994 remains underappreciated because of: 1) its novel oral delivery, 2) its well-understood standard-of-care class (carbapenem), and 3) a robust existing dataset which we think helps de-risk the potential of success for the Phase 3 trial." In its February 5, 2019 analyst report, Oppenheimer reiterated its Outperform rating and was encouraged by the significant progress at Spero, especially in regards to, among other things, "FDA acceptance of an IND," "meeting with FDA indicating that a single pivotal trial (ADAPT-PO) could support registration of SPR994," and "near-term initiation of the SPR994 Ph3 study."

(g) After Spero announced that the FDA granted Fast Track Designation for SPR 994, analysts continued to tout its development. For example, in its March 29, 2019 analyst report, Cantor Fitzgerald reiterated its Overweight rating and $27 price target stating, "This is positive news, in our view, and supports our belief that SPRO's efficient development pathway for SPR994 is still underappreciated."

(h) Analyst positivity continued when Spero announced positive incremental SPR994 PK data in June 2019. In its June 26, 2019 analyst report, Cantor Fitzgerald recognized the positive data and reported "increased confidence in the market opportunity for SPR994" after meeting with Spero's top executives, including Defendant Mahadevia.

(i) On October 3, 2019, Spero announced that an independent review committee that evaluated the lead-in PK data following enrollment of the first 70 patients in the ADAPT-PO Trial recommended that the trial continue with the same dose without modification. Analysts reacted favorably to this news, which they viewed as a significant de-risking event. Specifically, in its October 3, 2019 analyst report, Janney expressed its belief that "there is a high probability SPR994 will demonstrate equivalence to the trial's comparator antibiotic, IV-ertapenem [and as] a result, SPR994 has the potential to be the only approved oral carbapenem for cUTI." In its October 3, 2019 analyst report, Oppenheimer added that "numerous academic analysis have demonstrated a high level of concordance between PK/target attainment and successful Phase III results for anti-infective compounds."

(j) On May 5, 2020, Spero announced that the last patient was enrolled in the ADAPT-PO Trial. Analysts viewed completion of enrolment as another de-risking milestone that further supported the expectation of a positive result from the trial. For example, in its May 5, 2020 analyst report, Oppenheimer stated that "[g]iven the challenge of enrolling clinical trials during the COVID-19 pandemic, we view completion of enrollment as a significant de-risking milestone for the shares of SPRO." In a May 6, 2020 analyst report, H.C. Wainwright & Co. reiterated its buy rating after the announcement of completion of enrollment in the ADAPT-PO Trial.

(k) As the Class Period began on September 8, 2020, analysts were keenly focused on the ADAPT-PO Trial. Analysts, including Cantor Fitzgerald, Oppenheimer and Cowen, all

reacted very favorably to Spero's announcement of "positive" ADAPT-PO Trial top-line data. Cowen was "very impressed" with the data and viewed FDA approval as likely. Cantor Fitzgerald described the data as "clearly good news for SPRO" which underscored its "belief that SPRO's pipeline is underappreciated" and stated "[t]he much-anticipated data from this head-to-head comparison against an IV standard-of-care carbapenem antibiotic suggest that in many instances oral, outpatient treatment of these complicated bacterial infections is a viable option." Oppenheimer described the published data as "pristine" and saw no notable barriers to approval.

45. Thus, heading into the Class Period, the market was keenly focused on Defendants' public statements regarding Spero's ability to obtain FDA approval for tebipenem HBr, using the data created by the ADAPT-PO Trial, and bring it to market. Indeed, analysts covering Spero repeatedly discussed developments regarding the ADAPT-PO Trial, the tebipenem HBr NDA, and Defendants' work with the FDA to seek tebipenem HBr's approval as key drivers of both positive news (*e.g.*, as pled in connection with specific misstatements and omissions in the "Materially False and Misleading Statements & Omissions" section, *infra*) and negative news (*e.g.*, as pled in connection with specific partial corrective disclosures in the "Partial Corrective Disclosures Incrementally Revealed The Frauds" section, *infra*).

### D. Undisclosed, Material, Negative Facts

46. All of the concealed, non-public facts and circumstances set forth herein stand in stark contrast to Defendants' Class Period statements and render them materially false and misleading and actionable under the claims pled herein.

#### 1. *Undisclosed Facts And Risks Described By The CWs*

47. Unbeknownst to investors, there were deficiencies in the NDA for tebipenem HBr, particularly with the patient enrollment. These issues were known to Defendants during the Class Period and were evidenced, *inter alia*, by regular and numerous meetings with and comments from

the FDA. Only after the Individual Defendants had been given lavish executive compensation increases and bonuses and Defendant Mahadevia had engaged in substantial insider trading at fraud-inflated stock prices were the underlying negative facts and trends revealed concerning infirmities within the ADAPT-PO Trial patient enrollment and the inability of the ADAPT-PO trial data to support FDA approval, negatively impacting Spero's stock price.

48. CW1, Spero's Director of Clinical Data Management, said that the NDA for tebipenem HBr was in the FDA's Fast Track approval program, which is designated for drugs that could potentially treat serious conditions and fill and unmet medical need. CW1 stated that the program moves an application through the approval-seeking process at a much quicker pace than standard applications. CW1 said that, due to the speed, the FDA remains in much greater and frequent contact with applicants so that they can keep the application moving quickly. As CW1 stated, "My experience with Fast Track, the FDA, they hold your hand through the whole (process). They'll tell you, 'You're missing this,' and 'You need to have that.' Whatever needs to be done. Because they are fast-tracking it." CW1 described the FDA's rejection of the NDA for tebipenem HBr as surprising. Moreover, CW1 said that the fact that Spero let CW1 quit in February 2022, not long before FDA's letter of deficiency, without any effort to keep CW1, was odd. As CW1 stated, "That made me suspicious. Maybe they knew this was coming."

49. CW2, an Associate Director in the Spero Regulatory Affairs Department, worked to help the company respond to the FDA's inquiries and requests about the tebipenem HBr NDA. CW2 said that when questions or requests from the FDA came in, Spero employees with relevant expertise determined what information and / or data the company needed to gather to respond, at which point CW2's job was to gather that information. CW2 said that by December 2021, the FDA was requesting information about clinical, non-clinical, and CMC (Chemistry,

Manufacturing, and Control) issues. According to CW2, "Starting in December 2021, we got a lot of comments back from the FDA – requests for additional information on various topics: clinical, non-clinical, CMC [Chemistry, Manufacturing, and Control]. That continued through December. January and February – that was the peak. We got questions from them [the FDA] just about every week, even a couple times a week." CW2 added, "We just got so many questions. But a lot of them were clinical." CW2 said that Spero always responded in a timely manner before any deadlines. CW2 found that the amount of questions and requests by the FDA was significantly higher than CW2 was accustomed to seeing during an NDA process, after 20 years working in drug development and regulatory affairs, saying, "I felt it was weird that the FDA was asking all of those questions. In my experience, I didn't see that too much – as much as I did with this NDA and Spero." CW2 was surprised by the level of scrutiny and said the frequent questions made CW2 wonder if the NDA might be shaky. Due to CW2's responsibilities to gather and ensure proper submission of documents to the FDA, CW2 had access Spero's internal database storing all regulatory documents, including all the submissions to the FDA. CW2 said that in early April 2022, Ms. Liscouski gave CW2 an instruction from the "leadership team" to make all the FDA submission documents for tebipenem HBr confidential in the company's computer system to limit access to just a C-suite executive, three people in regulatory affairs (including CW2), two people in CMC (Chemistry, Manufacturing, and Control). CW2 said that as CEO, Defendant Mahadevia could ask for documents to be retrieved for himself at any time. CW2 recalls that Spero provided a response to the FDA in April 2022, but that it was not a big one.

50. CW3, a Lead Medical Science Liaison Director, described a March 2022 company-wide conference call that internally announced that the FDA had found deficiencies in the tebipenem HBr NDA, which CW3 said was a total surprise. CW3 said that company leadership

"did not want to comment on what it was" during the call and gave the impression that they were trying to respect the FDA. Only after being laid off did CW3 learn that the FDA reanalyzed the clinical trial data after removing all patients from the study who had tested for gram-positive bacteria. CW3 said that gram-positive bacteria like staphylococcus are different with differing cell wall structures from gram-negative bacteria like E. coli that commonly cause cUTI. CW3 confirmed that removing all the gram-positive patients meant that the evaluated patient population was smaller and the efficacy difference between tebipenem HBr and the comparative drug, IV ertapenem, was lower and did not meet the necessary noninferiority margin of 12.5%.

51. CW4, a Spero Medical Science Liaison, described the same March 2022 company-wide conference call as CW3, adding that it included Defendants Mahadevia and Shukla. CW4 said that on the call, top-level company leadership told employees that they had received a letter from the FDA citing deficiencies in the NDA for tebipenem HBr, but refused to disclose any details as to the nature of the deficiencies. As CW4 described company leadership, "They knew details of the deficiencies, but they were not going to share it. They didn't let you know if it was regarding the research, the manufacturing, nothing. There was no indication of what it could have been." CW4 said that leadership realized employees wanted more details but claimed that the FDA would view their discussing the deficiencies as "bad faith" that would hurt the approval process. CW4 said that company leadership told employees that everything would be fine, as CW4 put it: "They kept saying, 'We have a great team, we caught it early, it's early in the timing of the PDUFA, we feel comfortable we can work it out with FDA.'" CW4 said employees believed them, and CW4 was surprised to be laid off a month later.

52. CW5 and CW5's colleagues were shocked to learn that the FDA had removed patients from the evaluated population, which resulted in tebipenem HBr failing to meet its

noninferiority margin compared to IV ertapenem. CW5 was brought "into the tent," *i.e.*, knowing what was happening vis-à-vis the FDA, of Spero employees – including Ms. Liscouski and SVP of Clinical Angela Talley – who were preparing for Spero's Late Cycle Meeting (LCM) with the FDA. As CW5 stated, "That's why I know some of this stuff. It's not rumor." Due to CW5's work, CW5 understood that the FDA had questions and/or concerns regarding the clinical trial's inclusion within the evaluated population of patients infected with gram-positive bacteria, which FDA removed before re-analyzing the data without such patients. CW5 gleaned from discussions around the LCM meeting that the FDA wanted to remove patients infected with gram-positive bacteria because the comparison drug, IV ertapenem, was not indicated (*i.e.*, FDA approved) to treat gram-positive bacteria in cUTI. CW5 gathered market research regarding medical professionals' opinions concerning tebipenem HBr and how doctors planned to prescribe the drug if it was approved to support Spero's LCM presentation to alleviate FDA concerns that approving tebipenem HBr could lead to increased bacterial resistance to the carbapenem drug class. CW5's research showed that doctors intended to use tebipenem HBr as a last line treatment after other options had been tried and would not be widely prescribing tebipenem, which is how resistance can grow. From what CW5 understood, the FDA's thinking was that gram-positive bacteria are resistant to IV ertapenem, which would justify FDA's excluding gram-positive bacteria from the trial. So, another part of CW5's market research was gathered to show that gram-positive bacteria is not fully resistant to IV ertapenem, as evidenced by the success doctors had in treating gram-positive bacteria in cUTIs with IV ertapenem.

53. CW6 said that when Spero leadership told employees in March 2022 that the company had received a letter of deficiency from the FDA for the tebipenem HBr NDA, they did not disclose the actual deficiencies. Instead, CW6 said that leadership told employees of their

purported belief that the company could address the FDA's concerns before the PDUFA date in late June 2022. CW6 said, "They kept it very close to the vest" but trusted that it was for good reason. However, CW6 and CW6's colleagues were "stunned' at how fast the company shut down most operations and officially terminated so many employees immediately after the Late Cycle Meeting with the FDA. CW6 said that Spero's meeting with the FDA occurred on a Thursday and by the next Tuesday, the mass layoff was announced and employees learned that severance pay had been sent to their bank accounts. CW6 noted that such a large-scale layoff required coordination and planning among payroll, accounting, and leadership to get everything ready for such an abrupt action, leading CW6 to believe that the layoff was pre-planned. As CW6 stated, "Those plans had to be well under way to just pull the plug on all of us. It takes time to law that (action) out and run the numbers."

**2. *Undisclosed Facts And Risks Belatedly Admitted By Defendants***

54. As more fully discussed in the "Partial Corrective Disclosures Incrementally Revealed The Frauds" Section *infra*, Spero admitted that the ADAPT-PO Trial contained "deficiencies that preclude discussion of labeling and post-marketing requirements / commitments" with the FDA and that the trial's "data package may be insufficient to support approval" by the FDA. Specifically, the FDA's analysis of the ADAPT-PO Trial data indicated that the gram-positive patients were not part of the evaluable patient population and that their exclusion meant that the trial could not meet the required non-inferiority margin of -12.5% when tebipenem HBr was compared against IV ertapenem.

55. Whether any given patient was gram-positive or gram-negative was known upon their enrollment in the trial. Moreover, Defendants controlled the number of patients that were enrolled into the ADAPT-PO Trial and that contributed to the trial's data package. ***Despite the express, contrary recommendation of the trial's data review committee*** after its blinded

reassessment of the sample size after response data from 70% of patients was available, ***Defendants decided to proceed with the trial as enrolled***, with 1,372 patients – a number lower than the permissible maximum of 1,450 patients that the data review committee recommended. Thus, Defendants effectively self-selected their slim margin of error were any issue to arise within or concerning the patient population.

56. Moreover, as discussed in the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, Defendants had ample, ongoing opportunity to inquire about and confirm the sufficiency of the ADAPT-PO Trial's data package. Back on March 29, 2019 – 18 months before the Class Period – Spero announced that tebipenem HBr was granted Fast Track Designation by the FDA, a designation that facilitated development and expedites review of certain high-value drug candidates. Significantly, that designation provided Spero with the ability to interact ***more frequently*** with the FDA regarding tebipenem HBr's development and meant that its NDA would benefit from a ***rolling review*** by the FDA. This heightened access gave Defendants atypical access to the FDA, including for the purpose of discussing the sufficiency of the ADAPT-PO Trial's evaluable patient population and its ability to meet the non-inferiority margin.

57. Indeed, as early as September 2020, at the beginning of the Class Period, Defendant Mahadevia was publicly discussing the upcoming "***pre-NDA meetings***" (plural) with the FDA. By March 2021, Defendants publicly disclosed that at least one pre-NDA meeting had occurred and – including when directly asked by analysts – they expressly stated that they had ***discussed*** "***the format and content of the planned data package***" that would accompany the tebipenem HBr NDA and that they had "***received feedback***" from the FDA. In September 20221, Defendant Mahadevia was publicly discussing not only the pre-NDA meeting from March 2021, but also "multiple" prior FDA discussions that concerned whether the ADAPT-PO Trial could support the

NDA submission for tebipenem HBr. Coupled with the CW statements set forth *supra*, it is clear that Defendants had unusually significant and frequent access to the FDA ***throughout*** the Class Period, and that the LCM in April 2022 was the ***last*** – not the first – time that they delved into the ADAPT-PO Trials' patient population and non-inferiority margin data.

**E. Materially False and Misleading Statements & Omissions**

58. During the Class Period, Defendants made materially false and misleading statements and omissions that can be organized into three primary threads of the alleged fraud: (i) the Business Operations & Clinical Trial Fraud; (ii) the Reported Results Fraud; and (iii) the Internal Controls Fraud.

**1. *Business Operations & Clinical Trial Fraud***

59. The Class Period begins on September 8, 2020, when Defendants made a series of false and misleading statements and omissions regarding the results of the ADAPT-PO Trial of tebipenem HBr.

(a) On September 8, 2020, Spero filed with the SEC a Form 8-K (the "9/8/2020 Form 8-K"), signed by Stephen J. DiPalma ("DiPalma"), Spero's interim CFO, announcing top-line results for its ADAPT-PO Trial of oral tebipenem HBr. The 9/8/2020 Form 8-K stated,

> ***The pivotal Phase 3 clinical trial of oral tebipenem HBr met the primary endpoint, demonstrating statistical non-inferiority versus IV ertapenem.*** The primary endpoint of the trial was defined as the overall response rate (combined clinical cure plus microbiological eradication) at the test-of-cure ("TOC") visit in the microbiological-intent-to-treat population ("micro-ITT"). ***Favorable overall response rates at TOC were 58.8% versus 61.6% for tebipenem HBr and ertapenem, respectively (treatment difference, -3.3%; 95% confidence interval [CI]: -9.7, 3.2; -12.5% NI margin).*** Clinical cure rates at TOC were high, at greater than 93% in both treatment groups, and overall response rates were consistent across key subgroups of interest.
>
> *****
>
> The ***primary endpoint*** was the overall response, defined as the combination of clinical cure and microbiological eradication of the causative pathogen(s), at the

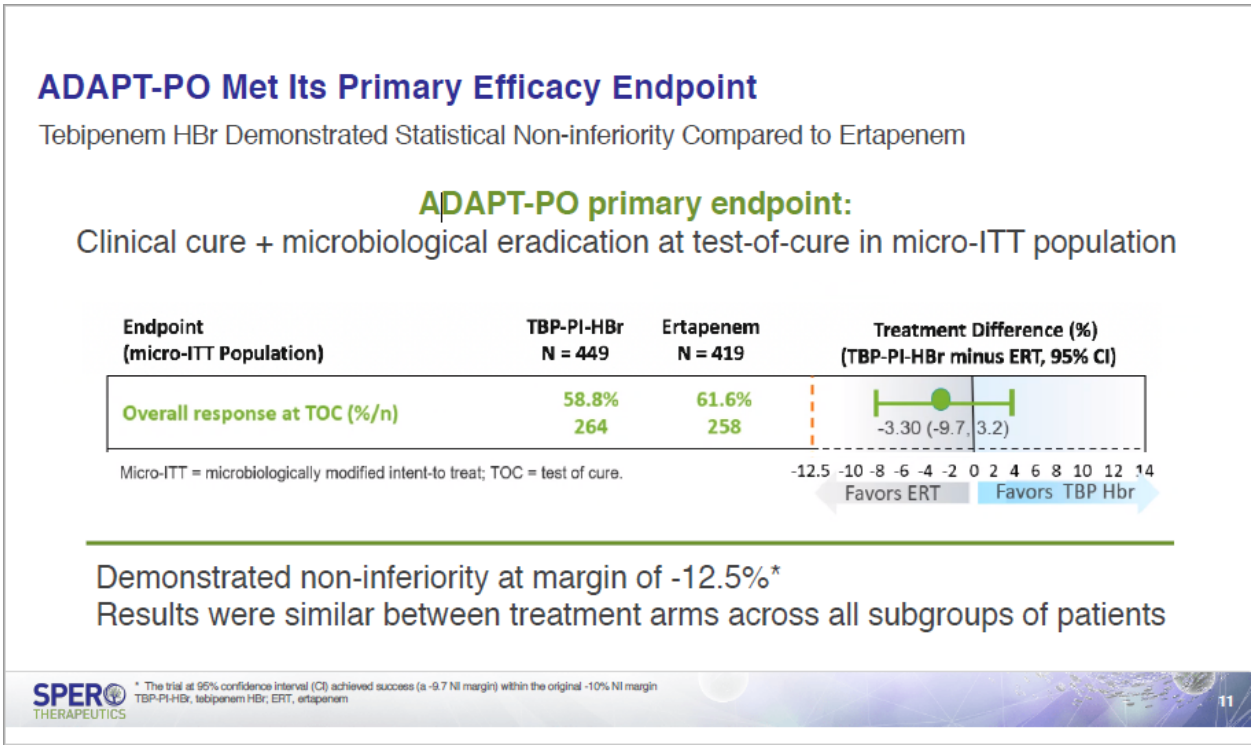
> TOC visit (Day 19, plus or minus 2 days) and was ***assessed in the micro-ITT population***. The primary analysis and assessment of non-inferiority was evaluated using a pre-specified -12.5% non-inferiority ("NI") margin. This NI margin was a modification of the original NI margin of -10% that was discussed with the U.S. Food and Drug Administration ("FDA") because of concern that the COVID-19 pandemic could have an adverse effect on the trial. As a result, the NI margin was modified prior to database lock from the original NI margin. However, as noted by the lower bound of the 95% confidence interval (-9.7), ***the trial also achieved success according to the original -10% NI margin***.
>
> The Company plans to present emerging data from tebipenem HBr program, including the ADAPT-PO clinical trial results, in detail at future scientific meetings and in publications. The ***Company intends to initiate a rolling New Drug Application ("NDA") submission and anticipates completing the NDA submission to the FDA for tebipenem HBr in the second quarter of 2021.***

(b) The 9/8/2020 Form 8-K attached as Exhibit 99.1 an investor presentation titled "Spero Therapeutics ADAPT-PO Phase 3 Topline Data Conference Call" (the "9/8/2020 Presentation Slides"). The 9/8/2020 Presentation Slides touted the "landmark" ADAPT-PO Trial results as "***Robust***," and reiterated that the results support an NDA submission in 2Q21 stating, "***ADAPT-PO Met Primary Endpoint***," "***Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin***)." They added, "tebipenem HBr, as the first oral carbapenem, could allow ***appropriate patients*** the opportunity to receive treatment in the community setting." They highlighted that "***ADAPT-PO Met Its Primary Efficacy Endpoint: Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem…at margin of -12.5%"*** based on analyses of the micro-ITT Population and that the "***Results were similar between treatment arms across all subgroups of patients***" as shown in Figure 1(a)[2] below. They stated that "ADAPT-PO Key Secondary Endpoints Support Robust Patient Outcomes: ***Clinical cure rates at [TOC] for micro-ITT groups comparable***

[2] Defendants repeatedly referenced this figure throughout the Class Period. Herein, it will be referred to as Figure 1, with consecutive lettering added for each instance it is referenced.

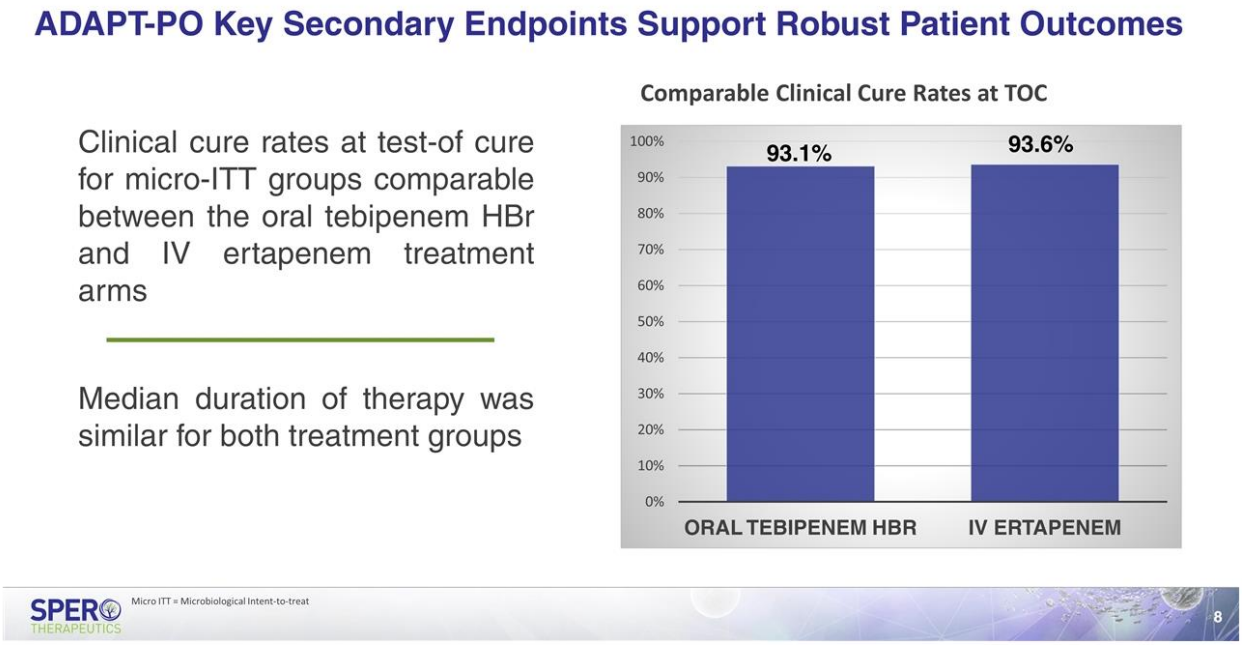
***between the oral tebipenem HBr and IV ertapenem treatment arms***" as shown in Figure 2(a)[3] below. They described the ADAPT-PO Trial as the "***One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions***" and stated, "***Positive ADAPT-PO Trial Results Support an NDA submission in 2Q21***." They also stated that Spero was "***Funded into the first quarter of 2022, through the NDA submission and the approval process for tebipenem HBr***," ***"BARDA/DTRA non-dilutive funding award for tebipenem HBr up to $56.7M"*** with ***"additional awards and alliances provid[ing] funding for the pipeline,***" and that "***Tebipenem HBr Well Positioned to Recognize Significant Market Opportunity***."

*Figure 1(a):*




[3] Defendants repeatedly referenced this figure throughout the Class Period. Herein, it will be referred to as Figure 2, with consecutive lettering added for each instance it is referenced.

*Figure 2(a):*




(c) The 9/8/2020 Form 8-K also attached as Exhibit 99.2 a press release (the "9/8/2020 Press Release") which reiterated the false and misleading statements contained in the 9/8/2020 Form 8-K. It stated, "***[r]esults demonstrate that tebipenem HBr was non-inferior compared to ertapenem with respect to the trial's primary endpoint, overall response (combined clinical cure plus microbiologic eradication) at the test-of-cure (TOC) visit in the microbiological-intent-to-treat (micro-ITT) population***." It added, "The ***favorable overall response rates were 58.8% (264/449) versus 61.6% (258/419) for tebipenem HBr and ertapenem, respectively (treatment difference, -3.3%; 95% confidence interval [CI]: -9.7, 3.2; -12.5% NI margin***)." It also said, "***Clinical cure rates at TOC were high (>93%) in both treatment groups***," ***Overall response rates were consistent across key subgroups of interest***, including age, ***baseline diagnosis, and presence of bacteremia***," and ***"[p]er pathogen microbiological response was balanced across treatment groups for most prevalent uropathogens***." It added, "Spero intends to initiate a rolling NDA submission and anticipates completing the NDA submission to the FDA

for tebipenem HBr in the second quarter of 2021." Defendant Mahadevia called the trial "landmark" and said the results were "***positive***" and "***demonstrate the value of tebipenem HBr***."

60. The misrepresentations and omissions in the 9/8/2020 Form 8-K, 9/8/2020 Presentation Slides, and 9/8/2020 Press Release, as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

61. On September 14, 2020, Defendants filed with the SEC a Prospectus Supplement ("9/14/2020 Prospectus Supplement") to the December 3, 2018 Prospectus. The 9/14/2020 Prospectus Supplement called tebipenem HBr Spero's "most advanced product candidate" and touted the "***positive topline results for the Phase 3 ADAPT-PO clinical trial of oral tebipenem HBr in complicated urinary track infection and acute pyelonephritis***." It declared that "[t]he ***pivotal Phase 3 clinical trial of oral tebipenem HBr met the primary endpoint, demonstrating statistical non-inferiority versus IV ertapenem.***" As such, Spero "intend[ed] to initiate a rolling New Drug Application (NDA) submission and anticipate[d] completing the NDA submission to the FDA for tebipenem HBr in the second quarter of 2021."

62. The misrepresentations and omissions in the 9/14/2020 Prospectus Supplement, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants'

Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

63. On September 16, 2020, Spero filed with the SEC an updated investor presentation titled "Spero Therapeutics Corporate Presentation Cantor Healthcare Conference" (the "9/16/2020 Cantor Slides") as Exhibit 99.1 to Form 8-K (the "9/16/2020 Form 8-K") signed by DiPalma. On information and belief, given their contents which presented the ADAPT-PO Trial results to analysts covering Spero, the 9/16/2020 Slides were authorized and approved by Defendant Mahadevia. The 9/16/2020 Cantor Slides were used in general corporate presentations, were posted on Spero's website, and were distributed by Spero in hardcopy or electronic form. They touted the "landmark" ADAPT-PO Trial results as "***Robust***" and said, "***ADAPT-PO Met Primary Endpoint***" and "***Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin***)." They added, "Tebipenem HBr, as the first oral carbapenem, could allow ***appropriate patients*** the opportunity to receive treatment in the community setting." The 9/16/2020 Cantor Slides also highlighted that "***ADAPT-PO Met Its Primary Efficacy Endpoint: Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem…at margin of -12.5%"*** based on analyses of the micro-ITT population and that the "***Results were similar between treatment arms across all subgroups of patients***" as shown in Figure 1(b) below. They stated that "ADAPT-PO Key Secondary Endpoints Support Robust Patient Outcomes: ***Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms***" as shown in

Figure 2(b) below. They called the ADAPT-PO Trial the "***One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions***" and stated, "***Positive ADAPT-PO Trial Results Support an NDA submission in 2Q21***." They also stated that Spero was "***Funded into the first quarter of 2022, through the NDA submission and the approval process for tebipenem HBr***," ***"BARDA/DTRA non-dilutive funding award for tebipenem HBr up to $56.7M"*** with ***"additional awards and alliances provid[ing] funding for the pipeline,***" and that "***Tebipenem HBr Well Positioned to Recognize Significant Market Opportunity***."

*Figure 1(b):*

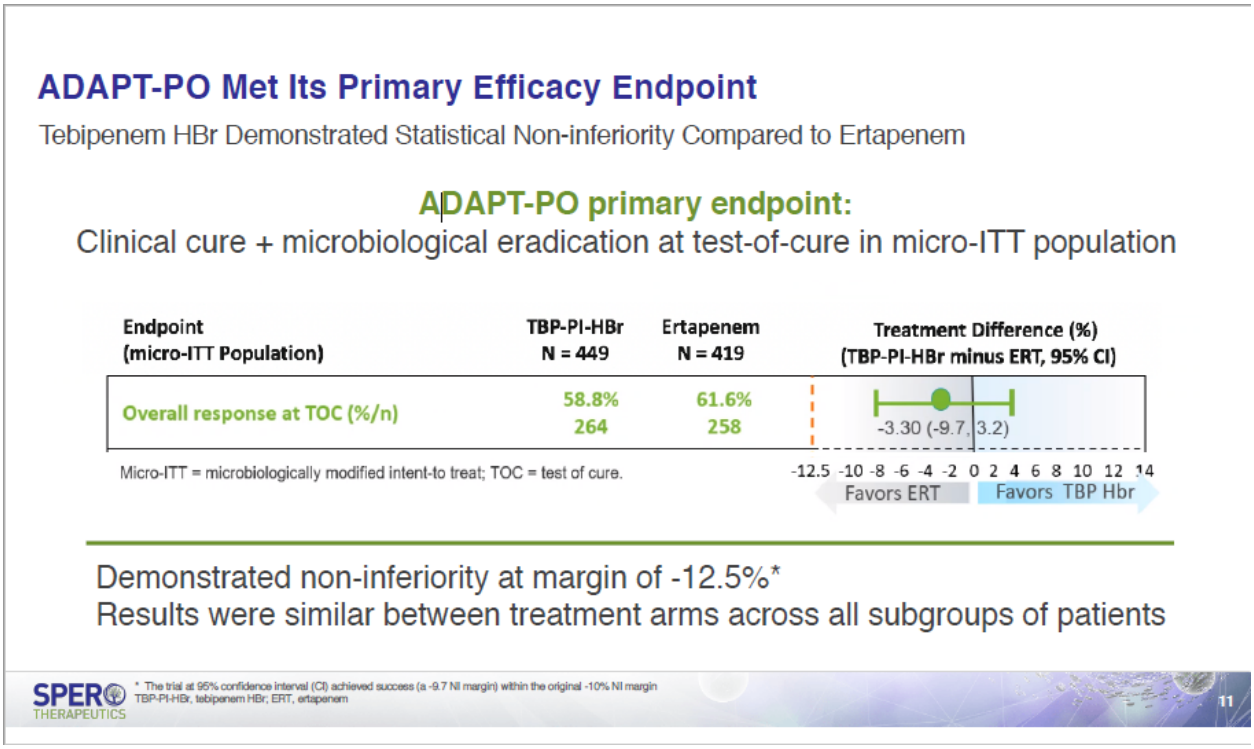
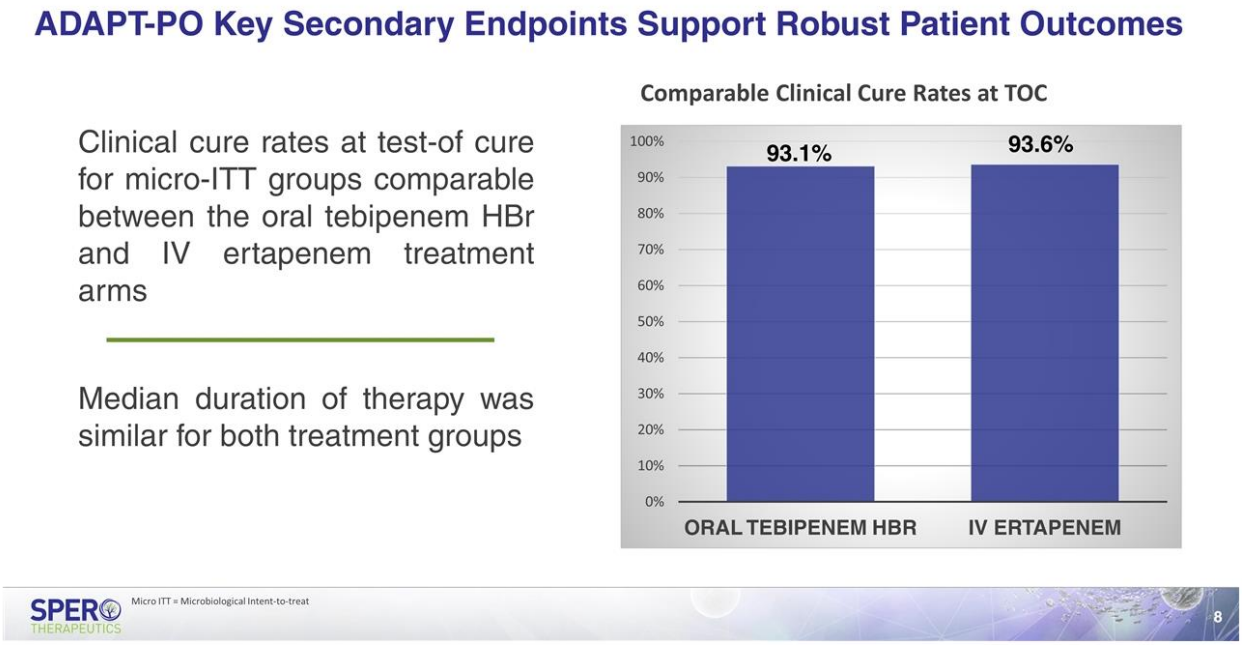


*Figure 2(b):*




64. The misrepresentations and omissions in the 9/16/2020 Cantor Slides and the 9/16/2020 Form 8-K, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

65. On September 17, 2020, Defendant Mahadevia gave a presentation at the 2020 Cantor Virtual Global Healthcare Conference that took place September 15-17, 2020 (the "9/17/2020 Cantor Presentation"), as had been announced in a September 15, 2020 press release (the "9/15/2020 Press Release"). At the 9/17/2020 Cantor Presentation, Defendant Mahadevia's

prepared remarks stated that "***oral tebipenem is comparable in its effectiveness for cUTI patients to IV ertapenem meeting the minus 12.5 percent non-inferiority margin set up by the FDA***." He assured investors and analysts that Spero was on track to file an NDA for tebipenem HBr stating, "***[i]ts NDA submission is planned for the second quarter of 2021***," and "***we'll plan for a pre-NDA meeting with the FDA, as well as completing the ancillary Phase 1 trials that are required as part of that package – all of that is on track and it's consistent with our guidance of completing the filing in the second quarter of next year.***" He also tied Spero's fundraising to the purportedly positive ADAPT-PO Trial data by stating, "***On the heels of positive data***, we were fortunate to raise a follow-on financing and, you know, because of that and including our existing cash, we have a strong cash position – 71 million as of the last quarterly filing not including follow-on financing proceeds of $80 million."

66. The misrepresentations and omissions in the 9/17/2020 Cantor Presentation, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

67. On September 23, 2020, Defendant Mahadevia gave a presentation at Oppenheimer's Fall Healthcare Life Sciences & MedTech Summit that took place September 21-23, 2020 (the "9/23/2020 Oppenheimer Presentation"), as had been announced in the 9/15/2020 Press Release. Defendant Mahadevia's prepared remarks stated, "***ADAPT-PO met its primary***

***endpoint…[e]ssentially demonstrating that an all-oral regimen for this seriously ill patient population can do the job of an IV***," "***the overall response rate of the cUTI population was comparable to IV ertapenem response rate within the non-inferiority margin set out by the FDA***," and "***[i]t is no small feat to have gotten an oral to do the job of an IV***." He emphasized the testing rigor required by the FDA, stating "what we were looking for was 17 to 21 days after the first dose we had these patients back, we measured both how they felt based on a FDA mandated questionnaire, as well as measured the microbial burden in their urine [as the] FDA requires." He added, "***[T]he treatment difference between tebipenem and ertapenem was 3.3%***" and "***what the FDA is looking for is the lower bound of that 95% confidence interval is greater than -12.5% and as you can see here, we did clear that…very high bar…given this was an all oral regimen in a very ill population***." He touted the ADAPT-PO Trial's results, highlighting the patient population studied without providing breakdown by gram-positive and gram-negative pathogens, stating, "***[T]he study was representative of the patients that we aimed to treat***" and "***the representative diagnoses of both lower UTI as well as acute pyelonephritis…represents a very tough test for tebipenem – No. 1, given the high proportion of lower UTI patients which tend to respond less well to therapy and No. 2, the 19 percent of patients that that met modified service criteria which means that they were quite ill***." He added, "***So, this was a sicker patient population with a high proportion of resistant pathogens and our all oral medication was able to do the job***." Defendant Mahadevia reiterated reassurances as to the tebipenem HBr NDA, stating, "***[W]e're working hard to get our NDA submission in as planned by the second quarter of 2021***" and "***[w]e have pre-NDA meetings coming up as part of that cadence, and we are rapidly working to complete any ancillary Phase 1 trials that would support the NDA***." During

the Q&A session, in response to the analyst question about other uses for tebipenem HBr, Defendant Mahadevia stated,

> Yeah, so more broadly I would say that, you know, ***our first focus is ensuring that tebipenem gets approved for complicated UTI*** and we're working hard filing that NDA. I would note that ***the notion that in cUTI patients we're able to show that oral tebipenem has the same effectiveness as IV ertapenem certainly builds a wide range of possibilities.*** Ertapenem is not just used in cUTI it's also used for patients with lung infections, intraabdominal infections, and a variety of other Gram-negative infections. And so there certainly is an opportunity to think about tebipenem being applicable where ertapenem is or where other oral antibiotics have failed.

68. The misrepresentations and omissions in the 9/23/2020 Oppenheimer Presentation, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

69. On September 24, 2020, Spero issued a press release (the "9/24/2020 Press Release"), announcing that it would host an analyst and investor call on September 30, 2020 (the "9/30/2020 KOL Call") about the treatment of cUTI with oral tebipenem HBr during which a Key Opinion Leader (KOL), Keith Kaye, MD, MPH, would present and Spero management would discuss the ADAPT-PO Trial top-line data. The 9/24/2020 Press Release added, "***ADAPT-PO trial met its primary endpoint of demonstrating that oral tebipenem HBr is statistically non-inferior to intravenous ertapenem***." During the 9/30/2020 KOL Call, Defendants said "***tebipenem HBr could fulfill an important niche in cUTI***," "***Spero continues to estimate it will***

***begin a rolling submission of the NDA in 1Q21, with a final submission planned 2Q21 based on the positive Phase 3 data***," and "***Spero is currently doing market research to prepare for the commercial launch of tebipenem HBr in the US***."

70. The misrepresentations and omissions in the 9/24/2020 Press Release and 9/30/2020 KOL Call, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

71. On October 16, 2020, Spero issued a press release (the "10/16/2020 Press Release) announcing presentations at the Infectious Disease Society of America (IDSA) IDWeek 2020 meeting to be held October 21-25, 2020, which touted the "positive" top-line data from the ADAPT-PO Trial "demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous (IV) ertapenem in the treatment of patients with cUTI and patients with AP." The 10/16/2020 Press Release provided a link to presentation slides (the "2020 IDWeek Slides") and several presentation posters (collectively, the "2020 IDWeek Posters") on Spero's website.

(a) The 10/16/2020 Press Release provided a link to the 2020 IDWeek Slides titled "Oral Tebipenem is Non-Inferior to IV Ertapenem in Complicated Urinary Tract Infection (cUTI) and Acute Pyelonephritis (AP): Results From the Pivotal ADAPT-PO Study." The 2020

IDWeek Slides displayed the micro-ITT population in Figure 3(a)[4] below. They displayed the percentages of patients in micro-ITT broken down by gram-negative pathogens and gram-positive pathogens in Figure 4(a)[5] below. They displayed the per-pathogen microbiological eradication at test-of-cure for the gram-negative pathogens (Enterobacterales), which was 63.0% in tebipenem HBr and 65.9% in ertapenem as shown in Figure 5(a)[6] below. They concluded that based on the data from the micro-ITT population, "***ADAPT-PO Met the Primary Efficacy Endpoint***" and that "***Oral TBP-PI-HBr was non-inferior to IV ertapenem in overall response at TOC***" as shown in Figure 6(a)[7] below. They touted the ADAPT-PO Trial's results regarding the non-inferiority to ertapenem by stating, "***Oral TBP-PI-HBr*** (600mg PO q8h) ***was non-inferior to ertapenem*** (1g IV q24h***) in the treatment of hospitalized adult patients with cUTI/AP***," "***ADAPT-PO achieved all primary and secondary objectives***," and "***These effects were seen consistently across patient subsets***." The 2020 IDWeek Slides also confirmed that the NDA submission was on track stating, "***Spero expects that data from this single pivotal trial will support submission of an NDA***."

[4] Defendants repeatedly referenced this figure throughout the Class Period. Herein, it will be referred to as Figure 3, with consecutive lettering added for each instance it is referenced.

[5] Defendants repeatedly referenced this figure throughout the Class Period. Herein, it will be referred to as Figure 4, with consecutive lettering added for each instance it is referenced.

[6] Defendants repeatedly referenced this figure throughout the Class Period. Herein, it will be referred to as Figure 5, with consecutive lettering added for each instance it is referenced.

[7] Defendants repeatedly referenced this figure throughout the Class Period. Herein, it will be referred to as Figure 6, with consecutive lettering added for each instance it is referenced.

*Figure 3(a):*

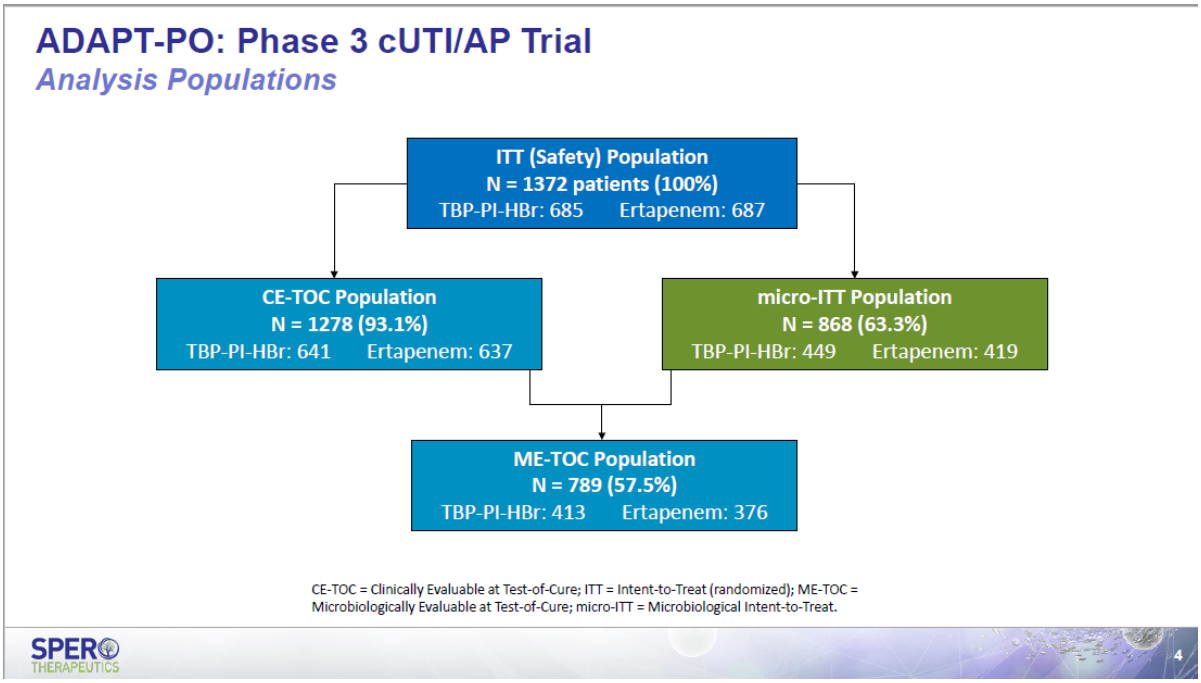



*Figure 4(a):*

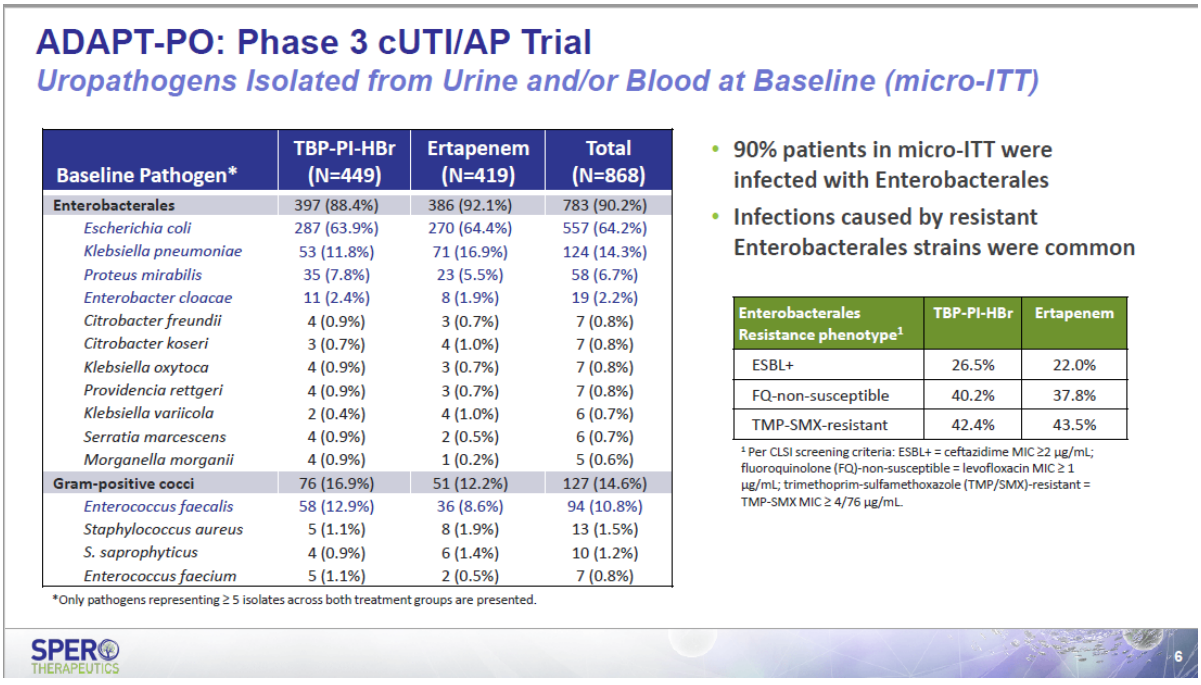


*Figure 5(a):*

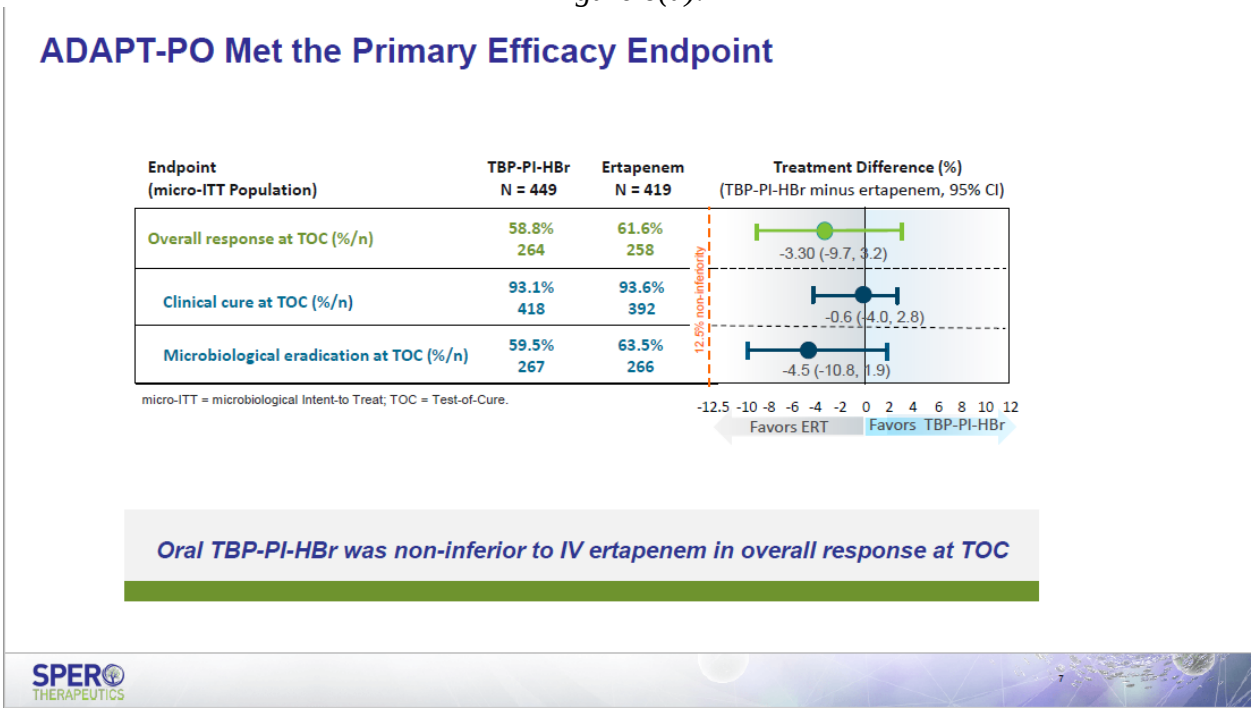
## ADAPT-PO: Phase 3 cUTI/AP Trial

### *Per-Pathogen Microbiological Eradication at TOC (micro-ITT)*

| Baseline Pathogen | TBP-PI-HBr N=449 % (n/N1) | Ertapenem N=419 % (n/N1) |
|---|---|---|
| **Enterobacterales*** | 320/508 (63.0%) | 337/511 (65.9%) |
| *E. coli* | 230/355 (64.8%) | 229/352 (65.1%) |
| *K. pneumoniae* | 35/65 (53.8%) | 52/78 (66.7%) |
| *P. mirabilis* | 23/42 (54.8%) | 21/31 (67.7%) |
| *E. cloacae* | 7/12 (58.3%) | 4/8 (50.0%) |
| **Resistant Enterobacterales Phenotypes** | | |
| ESBL+ | 57/105 (54.3%) | 53/85 (62.4%) |
| FQ-NS | 86/159 (54.1%) | 90/146 (61.6%) |
| TMP-SMX-R | 96/168 (57.1%) | 108/168 (64.3%) |

*Only pathogens with ≥ 5 isolates in either treatment group are presented.
ESBL+ = Expended-spectrum β-lactamase-producing; FQ-NS = fluoroquinolone-nonsusceptible; TMP-SMX-R = trimethoprim-sulfamethoxazole-resistant.

*Figure 6(a):*




(b) The 10/16/2020 Press Release provided a link to presentation poster #1695 titled "Tebipenem: An Oral Carbapenem With Activity Against Multi-Drug Resistant Urinary

Tract Infection Isolates of *Escherichia Coli* Collected From US Medical Centers During 2019" (the "2020 IDWeek Poster 1695"), which assessed the activity of tebipenem against E. Coli collected from UTIs in the U.S. and touted the ADAPT-PO Trial's results by stating "***Tebipenem is an oral carbapenem that has recently demonstrated non-inferiority to IV ertapenem for the treatment of cUTI***" and "***Tebipenem represents a new oral option for cUTIs in an era of ESBL-mediated co-resistance to existing oral agents.***"[8]

(c) The 10/16/2020 Press Release also provided a link to presentation poster #1304 titled "Characterization of Tebipenem Pivoxil Hydrobromide Pharmacokinetics – Pharmacodynamics in a Neutropenic Murine Acute Pyelonephritis Model" (the "2020 IDWeek Poster 1304), which evaluated the pharmacokinetics of tebipenem and touted its effectiveness, stating that tebipenem HBr "***is a carbapenem with broad-spectrum activity against Gram-positive and -negative bacteria that is being developed for the treatment of patients with complicated urinary tract infections***."

72. The misrepresentations and omissions in the 10/16/2020 Press Release, 2020 IDWeek Slides, 2020 IDWeek Poster 1695, and 2020 IDWeek Poster 1304 as alleged in the preceding paragraphs were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating

[8] Here, "tebipenem" was used as a short-hand for tebipenem HBr as it references the purported ADAPT-PO Trial results for tebipenem HBr.

that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

73. Spero announced its Q3 2020 quarterly results in a series of public statements on November 5, 2020, which discussed Spero's development of tebipenem HBr and the results of the ADAPT-PO Trial.

(a) On November 5, 2020, Spero issued an earnings press release (the "11/5/2020 Earnings Release"), which was filed with the SEC as an exhibit to a Form 8-K filed the same day ("11/5/2020 Form 8-K") signed by DiPalma, announcing its financial and operating results for the quarter ended September 30, 2020. On information and belief, given their discussion of the ADAPT-PTO Trial and the fact that he was quoted therein, the 11/5/2020 Earnings Release and 11/5/2020 Form 8-K were authorized, approved, and written or edited by Defendant Mahadevia. In the 11/5/2020 Earnings Release, Defendant Mahadevia is quoted as saying, "[w]e made significant clinical progress in the third quarter with the announcement that the ADAPT-PO Trial met its primary endpoint." He continued by expressing that Spero is "excited by the ***positive results seen in the ADAPT-PO trial***" and that the results "***highlight the potential benefit oral tebipenem HBr could offer to patients with cUTI***."

(b) Also on November 5, 2020, Spero held an earnings call with analysts and investors in conjunction with its Q3 2020 financial results (the "11/5/2020 Earnings Call"), on which Defendant Mahadevia and DiPalma spoke. During prepared remarks, Defendant Mahadevia highlighted that Spero's "***ADAPT-PO Phase 3 trial met its primary endpoint with data demonstrating that oral tebipenem HBr is non-inferior to IV or dependent for the treatment of complicated urinary tract infections and acute pyelonephritis***." Defendant Mahadevia continued by stating that the "***positive results from this trial*** … are quite noteworthy as they show tebipenem

HBr can provide the convenience of an oral therapy without making any compromises on clinical response, safety or tolerability." In his prepared remarks, Defendant Mahadevia also emphasized that the ADAPT-PO Trial "results represent an important achievement not only for Spero, but also for the broader industry and our patients." Defendant Mahadevia ended his prepared remarks about tebipenem HBr by explaining that ***"[a]s previously discussed with FDA, positive results in the single, well-controlled pivotal trial could be sufficient to support the approval of a new drug application or NDA for tebipenem HBr***" and reiterating the Spero "***continue[s] to expect to make an NDA submission to the FDA in the second quarter of 2021***." In response to an analyst question regarding the impact COVID had on Spero's clinical trials, Defendant Mahadevia said "[f]ortunately, for us we have been able to, with an excellent clinical operations team, manage that well and ***we're able to deliver ADAPT-PO on time with high-quality data***, number one. And number two, ***also the Phase 1 studies that were outstanding for the filing of the NDA***." In response to an analyst question regarding the remaining required items for filing the NDA, Defendant Mahadevia explained that "the three parts to filing the NDA," including the ADAPT-PO Trial data, "***are on track as it relates to our overall timeline for NDA***."

(c) On November 5, 2020, Spero filed a Form 10-Q with the SEC for Q3 2020 (the "Q3 2020 10-Q"), signed and SOX-certified by Defendant Mahadevia and DiPalma.[9] When describing the nature of its business, Spero touted tebipenem HBR as Spero's "most advanced product candidate" that is "***designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections***." It also emphasized that "[t]reatment with effective orally administrable antibiotics may prevent hospitalizations for serious infections and

[9] As used herein, "SOX" refers to the Sarbanes-Oxley Act of 2002, which, among other things, imposed requirements on executives to personally certify certain corporate filings made with the SEC.

enable earlier, more convenient and cost-effective treatment of patients after hospitalization." Additionally, Spero touted "***positive topline results for the Phase 3 ADAPT-PO clinical trial of oral tebipenem HBr in [cUTI] and [AP]***" which "***met the primary endpoint demonstrating statistical non-inferiority versus IV ertapenem***." Further, Spero stated that the ADAPT-PO trial "comparative safety data from the 1,372 hospitalized adult patients who enrolled in the trial suggest that ***tebipenem HBr was well-tolerated, with a safety profile similar to that of ertapenem.***" Based on these results, Spero "***anticipate[d] submitting a New Drug Application for tebipenem HBr to the FDA in the second quarter of 2021***."

74. The misrepresentations and omissions in the 11/5/2020 Earnings Release, 11/5/2020 Form 8-K, 11/5/2020 Earnings Call, and Q3 2020 10-Q, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

75. On November 13, 2020, Defendants filed a Prospectus with the SEC ("11/13/2020 Prospectus"). The 11/13/2020 Prospectus Supplement touted tebipenem HBr as Spero's "most advanced product candidate" that "is designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections." Spero also expressed its belief that its "novel product candidates, if successfully developed and approved, would have a meaningful patient

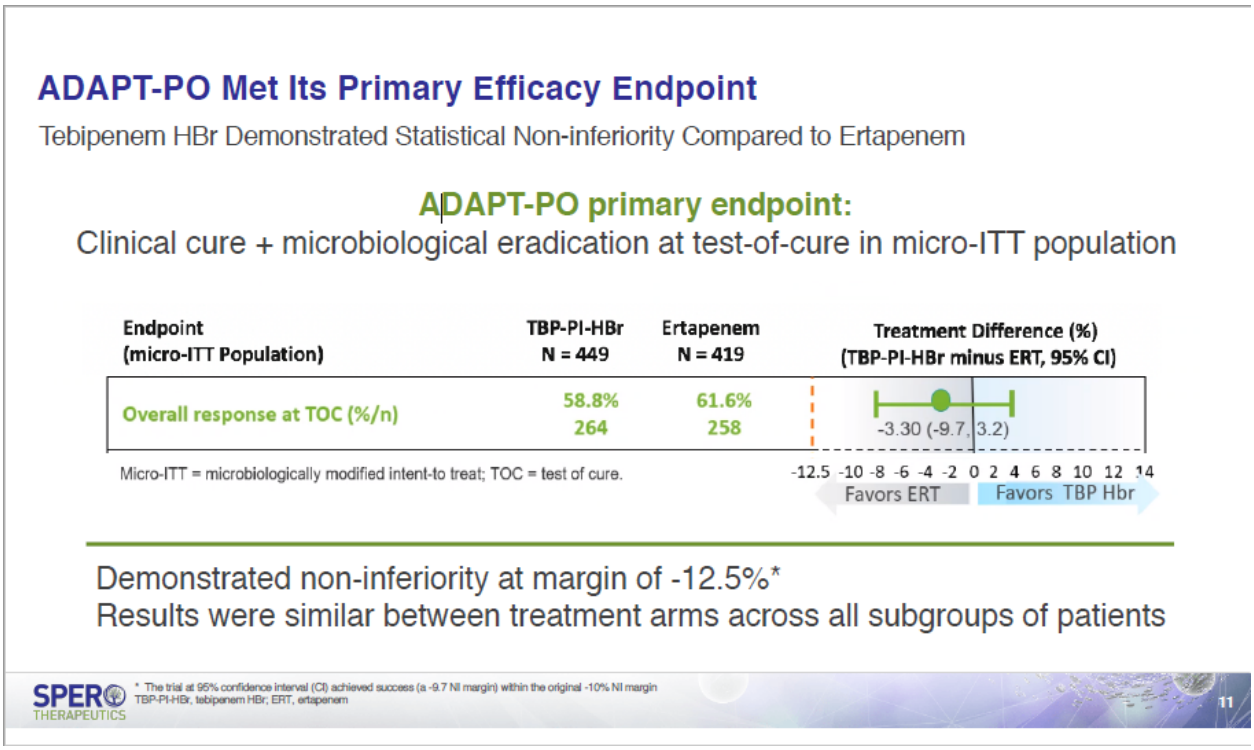
impact and significant commercial applications for the treatment of MDR infections in both the community and hospital settings."

76. The misrepresentations and omissions in the 11/13/2020 Prospectus Supplement, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section supra, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

77. On November 18, 2020, Spero gave a presentation at the 2020 Stifel Healthcare Conference that included a slide deck titled "Spero Therapeutics Corporate Presentation" (the "11/18/2020 Stifel Presentation"). It touted the "landmark" ADAPT-PO Trial results as "***Robust***," and reiterated that the results support an NDA submission in 2Q21 stating, "***ADAPT-PO Phase 3 met its primary endpoint in landmark trial – Oral tebipenem HBr demonstrated noninferiority to IV ertapenem in cUTI and AP, Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin***)." It added, "Tebipenem HBr, if approved as the first oral carbapenem, could allow ***appropriate patients*** the opportunity to receive treatment in the community setting," and "***Tebipenem has the Potential to be a Highly Differentiated Therapy, if Approved***." The 11/18/2020 Stifel Presentation also highlighted that "***Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem…at margin of -12.5%"*** based on analyses of the micro-ITT population and that the **"*Results were similar between treatment arms across all subgroups of patients*"** as

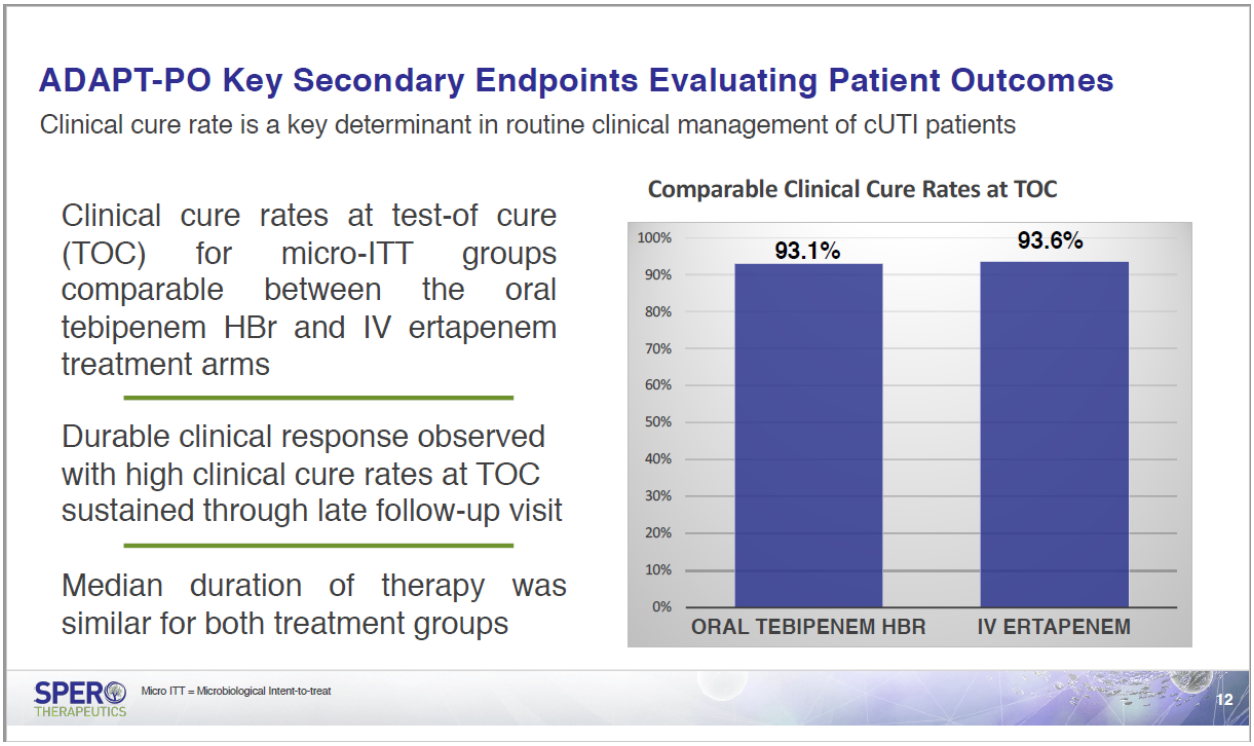
shown in Figure 1(c) below. It stated that "ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes: ***Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms***" as shown in Figure 7(a)[10] below. It also reiterated that the NDA submission was on track referring to the ADAPT-PO Trial as the "***One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions***" and stating, "***Positive ADAPT-PO Trial Results Support an NDA submission in 2Q21***." It also stated that Spero was "***Funded into the first quarter of 2022, through the NDA submission and the approval process for tebipenem HBr***," and ***"BARDA/DTRA non-dilutive funding award for tebipenem HBr up to $56.7M"*** with ***"additional awards and alliances provid[ing] funding for the pipeline.***"

*Figure 1(c):*




[10] Defendants repeatedly referenced this figure throughout the Class Period. Herein, it will be referred to as Figure 7, with consecutive lettering added for each instance it is referenced.

*Figure 7(a):*




78. The misrepresentations and omissions in the 11/18/2020 Stifel Presentation as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

79. On December 3, 2020, Spero issued a series of false and misleading statements regarding the results of the ADAPT-PO trial of tebipenem HBr and the sufficiency of the NDA that could have supported approval.

(a) On December 3, 2020, Spero filed with the SEC a Form 8-K (the "12/3/2020 Form 8-K") signed by DiPalma. On information and belief, given their discussion of the tebipenem HBr NDA and the company's cash position, the 12/3/2020 Form 8-K was authorized and approved by Defendant Mahadevia. It announced, "***The Company expects to complete the planned submission of its NDA for tebipenem HBr during the second half of 2021***." It added, ***"[T]he Company believes that its existing cash, cash equivalents and marketable securities, together with committed funding from its BARDA contract and other non-dilutive funding commitments, will be sufficient to fund its operating expenses and capital expenditure requirements into the second quarter of 2022, including through the submission of the NDA for tebipenem HBr."***

(b) On December 3, 2020, Spero filed with the SEC as Exhibit 99.1 to the 12/3/2020 Form 8-K an updated investor presentation titled "Spero Therapeutics Corporate Presentation Evercore ISI HealthCONx Conference" (the "12/3/2020 Evercore Slides"), which were used in general corporate presentations, were made available on Spero's website, and were distributed by Spero in hardcopy or electronic form. The 12/3/2020 Evercore Slides touted the ADAPT-PO Trial results as "***Robust***" and reiterated, "***ADAPT-PO Phase 3 met its primary endpoint in landmark trial – Oral tebipenem HBr demonstrated noninferiority to IV ertapenem in cUTI and AP, Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin***)." They added, "Tebipenem HBr, if approved as the first oral carbapenem, could allow ***appropriate patients*** the opportunity to receive treatment in the community setting." They highlighted that "***Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem…at margin of -12.5%"*** based on analyses of the micro-ITT population and that the **"*Results were similar between treatment***

***arms across all subgroups of patients*"** as shown in Figure 1(d) below. They stated, "ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes: ***Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms***" as shown in Figure 7(b) below. They referred to the ADAPT-PO Trial as the "***One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions***" and stated, "***Positive ADAPT-PO Trial Results Support an NDA submission in 2Q21***." They also stated that Spero was "***Funded into the second quarter of 2022, through the NDA submission for tebipenem HBr***" and touted the ***"BARDA/DTRA non-dilutive funding award for tebipenem HBr up to $56.7M"*** with ***"additional awards and alliances provid[ing] funding for the pipeline.***"

*Figure 1(d):*

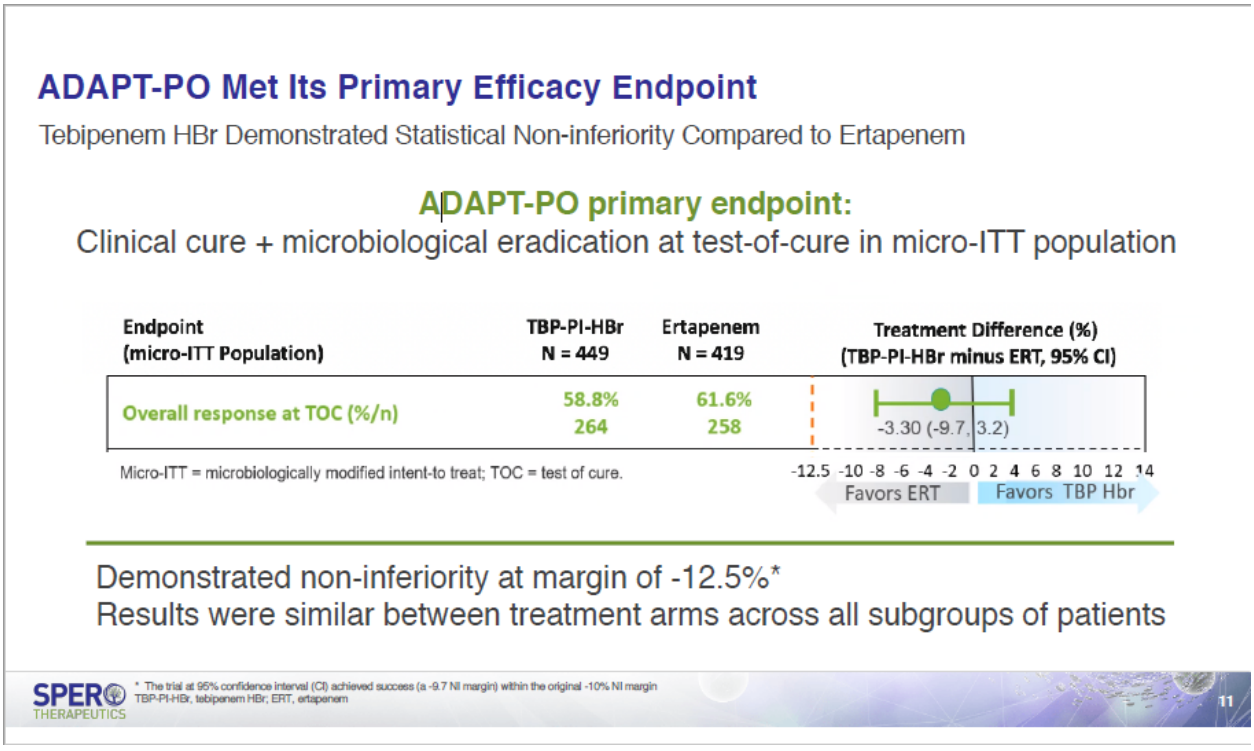
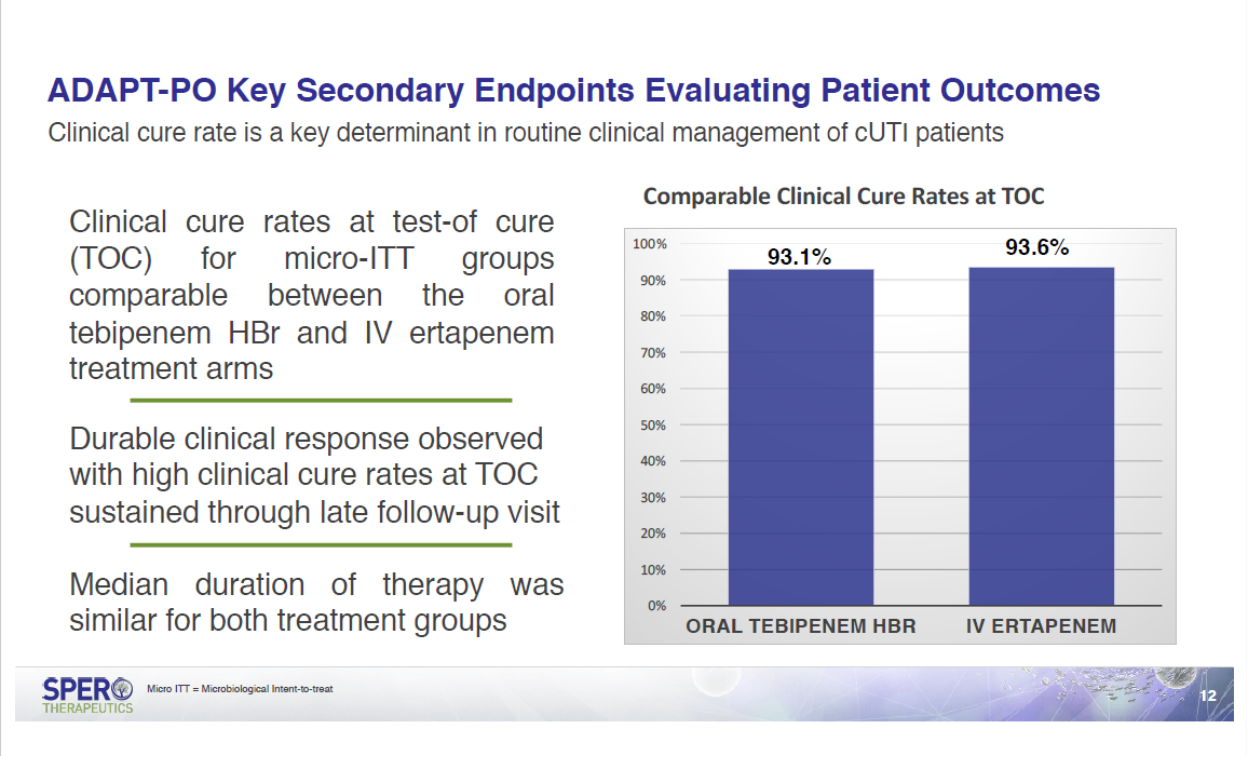


*Figure 7(b):*




(c) Also on December 3, 2020, Defendant Mahadevia gave a presentation at the 3rd Annual Evercore ISI HealthCONx Conference that took place December 1-3, 2020 (the "12/3/2020 Evercore Presentation"), as had been announced in a press release on November 30, 2020 (the "11/30/2020 Press Release"). During the presentation, Defendant Mahadevia touted the "***successful***" ADAPT-PO Trial results stating, "***both from a pharmacokinetic perspective and microbiological perspective and now a clinical perspective, we've shown that tebipenem behaves like a carbapenem in a pill***." He further stated,

> ***And what we've shown is that tebipenem is a carbapenem in a pill.*** And so we recently unveiled ADAPT-PO which is our Phase 3 study, the first ever of its kind and ***we compared this all oral regimen in a very sick population with cUTI against an all IV regimen***. ***We wanted to,*** both from a payer and a prescriber prospective, ***show that our oral regimen did the exact same thing as IV. And that is what the study showed both from an efficacy perspective***, but also from a tolerability prospective. And, ***we're hard at work on the NDA***.

In response to the analyst request to discuss unmet need in the out-patient gram-negative setting and whether the ESBL+ and other pathogens particularly resistant to antibiotics are driving it, Defendant Mahadevia stated, "along with ESBL where a typical form of resistance that these UTI bacteria pass to each other, there are a variety of other mechanisms that these bacteria have learned over a period of time to become resistant." In response to the analyst question regarding when Spero would provide more updates and what could investors and analysts expect from Spero over the next one to two years, Defendant Mahadevia stated, "***As we noted, you'll be looking for us to be providing further communication as we go in terms of the cadence of the NDA. Within that timeframe, we will also have had our pre-NDA discussion with FDA***."

80. The misrepresentations and omissions in the 12/3/2020 Form 8-K, 12/3/2020 Evercore Presentation, and 12/3/2020 Evercore Slides as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

81. On December 17, 2020, Spero issued a press release (the "12/17/2020 Press Release"), announcing the appointment of Defendant Shukla as Chief Financial Officer. Defendant Shukla was quoted therein as stating, "***With positive Phase 3 data for tebipenem HBr in September 2020 [], Spero is well positioned to realize its clinical, strategic and financial objectives***."

82. The misrepresentations and omissions in the 12/17/2020 Press Release, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

83. On January 21, 2021, Spero issued a press release (the "1/21/2021 Press Release"), announcing the issuance of a patent covering a crystalline formulation of tebipenem HBr. It touted the "***positive***" top-line results from the ADAPT-PO Trial. Defendant Mahadevia was quoted therein as stating, "***We remain focused on advancing oral tebipenem HBr towards a potential approval and look forward to submitting the New Drug Application for tebipenem HBr to the FDA in the second half of 2021***."

84. The misrepresentations and omissions in the 1/21/2021 Press Release, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

85. On March 11, 2021, Spero filed a Form S-3 Registration Statement with the SEC ("3/11/2021 Registration Statement"), signed by Defendants Mahadevia and Shukla. The 3/11/2021 Registration Statement touted tebipenem HBr as Spero's "most advanced product candidate" that "is ***designed to be the first oral carbapenem-class for use in adults to treat MDR Gram-negative infections***" that "may prevent hospitalizations for serious infections and enable earlier, more convenient and cost-effective treatment of patients after hospitalization."

86. The misrepresentations and omissions in the 3/11/2021 Registration Statement, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section supra, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

87. Spero announced its Q4 2020 quarterly and full year 2020 results in a series of public statements on March 11, 2021, which discussed Spero's development of tebipenem HBr.

(a) On March 11, 2021, Spero issued an earnings press release (the "3/11/2021 Earnings Release"), which was filed with the SEC as an exhibit to a Form 8-K filed the same day (the "3/11/2021 Form 8-K") signed by Spero's Chief Legal Officer Tamara Joseph ("Joseph"), announcing its financial and operating results for the quarter and year ended December 31, 2020. On information and belief, the 3/11/2021 Earnings Release and 3/11/2021 Form 8-K were authorized, approved, and written or edited by the Individual Defendants, given their discussion of the ADAPT-PO Trial and the FDA approval process for tebipenem HBr and given that

Defendant Mahadevia was quoted therein. In it, Defendant Mahadevia was quoted as saying that chief among Spero's yearly milestones "was our announcement in September 2020 that the ***tebipenem HBr ADAPT-PO Phase 3 clinical trial in complicated urinary tract infection … met its primary endpoint***." He also stated that "we look forward to another productive year in 2021, as we ***advance tebipenem HBr towards an NDA submission in the second half of 2021*** and move closer to potentially addressing the unmet needs of the estimated 2.7 million cUTI and AP patients in the United States."

(b) Also on March 11, 2021, Spero held an earnings call with analysts and investors in conjunction with its Q4 2020 and full year 2020 financial results (the "3/11/2021 Earnings Call"), on which Defendants Mahadevia and Shukla spoke. During prepared remarks, Defendant Mahadevia highlighted that Spero's "***primary focus remains tebipenem HBr's advancement towards commercialization following the positive ADAPT-PO Phase 3 trial results that we reported in September***." He continued by stating that ***"[t]hese results showed that the trial met its primary endpoint with data demonstrating that all oral regimen of tebipenem HBr is non-inferior to an all IV regimen or ertapenem for the treatment of complicated urinary tract infections, or cUTI, and acute pyelonephritis, or AP***." In his prepared remarks, Defendant Mahadevia also emphasized the design of the ADAPT-PO Trial by saying the following:

> We chose the design ADAPT-PO as the first head-to-head comparison of an all-oral and all-IV regimen in cUTI specifically to provide a robust result that would give physicians the confidence to prescribe tebipenem HBr to the millions of cUTI and AP patients who would otherwise receive IV therapy. We believe we have done just that as ***our data show that tebipenem HBr can provide the convenience of an oral therapy without making any compromises on clinical response safety or tolerability***. ***Based on our previous FDA interactions and written communication, positive results from this single well-controlled pivotal trial could be sufficient to support the approval of a new drug application, or NDA, for tebipenem HBr***.

Further, Defendant Mahadevia expressed that Spero "***continue[s] to expect to make an NDA submission to FDA for tebipenem HBr for the treatment of cUTI and AP in the second half of 2021***" and felt "***comfortable with this guidance … given that the Phase 3 and all supportive Phase 1 trials have been completed***." In response to an analyst question regarding possible tebipenem HBr post-marketing post-approval studies, Defendant Mahadevia stated that Spero is "focused on maximizing the value for tebipenem and cUTI" and described the ADAPT-PO Trial as "powerful in its own right."

(c) On March 11, 2021, Spero filed a Form 10-K with the SEC for Q4 2020 and year end 2020 (the "2020 10-K"), signed and SOX-certified by Defendants Mahadevia and Shukla. When describing the nature of its business, Defendants labeled tebipenem HBR as Spero's "most advanced product candidate" and touted several "key attributes" and "advantages" that "support our confidence in tebipenem HBr's commercial potential." Defendants also touted tebipenem HBr's safety and efficacy profile and its "potential to be a safe and effective treatment for cUTI and other serious and life-threatening infections," due to the purportedly "***positive topline data from the single pivotal Phase 3 clinical trial … that is required for approval of tebipenem HBr to treat complicated urinary tract infection***," which "***achieved its primary objective, demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous ertapenem in the treatment of patients with cUTI and patients with AP, with respect to the primary endpoint of overall response at the test-of-cure, or TOC, visit in the microbiological-intent-to-treat, or micro-ITT, population***." Defendants continued by stating that based on these results, Spero ***intended to make an NDA submission to the FDA for tebipenem HBr in the second half of 2021***. Defendants also stated that ***"[b]ased on our pre-IND, pre-Phase 3 meeting with the FDA, we***

***believe that positive results from a single Phase 3 clinical trial of tebipenem in cUTI would support the approval of tebipenem HBr for the treatment of cUTI***."

88. The misrepresentations and omissions in the 3/11/2021 Earnings Release, 3/11/2021 Form 8-K, 3/11/2021 Earnings Call, and 2020 10-K, as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

89. On March 16, 2021, Defendants Mahadevia and Shukla gave a presentation at the Oppenheimer 31st Annual Healthcare Conference that took place March 16-18, 2021 (the "3/16/2021 Oppenheimer Presentation"), as had been announced in a press release on February 25, 2021 (the "2/25/2021 Press Release") and on Oppenheimer's conference website. Their 3/16/2021 Oppenheimer Presentation included a slide deck (the "3/16/2021 Oppenheimer Slides"), which touted the "landmark" ADAPT-PO Trial results as "***Robust***," and reiterated that the "***ADAPT-PO Phase 3 met its primary endpoint in landmark trial – Oral tebipenem HBr demonstrated noninferiority to IV ertapenem in cUTI and AP, Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin***)." They added, "Tebipenem HBr, if approved as the first oral carbapenem, could allow ***appropriate patients*** the opportunity to receive treatment in the community setting." The 3/16/2021 Oppenheimer Conference Presentation Slides also highlighted that "***Tebipenem***

***HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem…at margin of -12.5%"*** based on analyses of the micro-ITT population and that the "***Results were similar between treatment arms across all subgroups of patients***" as shown in Figure 1(e) below. They stated, "ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes: ***Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms***" as shown in Figure 7(c) below. They also reiterated that the NDA submission was on track, referred to the ADAPT-PO Trial as the "***One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions***," and stated, "***Positive ADAPT-PO Trial Results Support an NDA submission in 2Q21***." They also stated that Spero was "***Funded into the second quarter of 2022, through the NDA submission for tebipenem HBr***," and ***"BARDA/DTRA non-dilutive funding award for tebipenem HBr up to $56.7M"*** with ***"additional awards and alliances provid[ing] funding for the pipeline.***"

*Figure 1(e):*

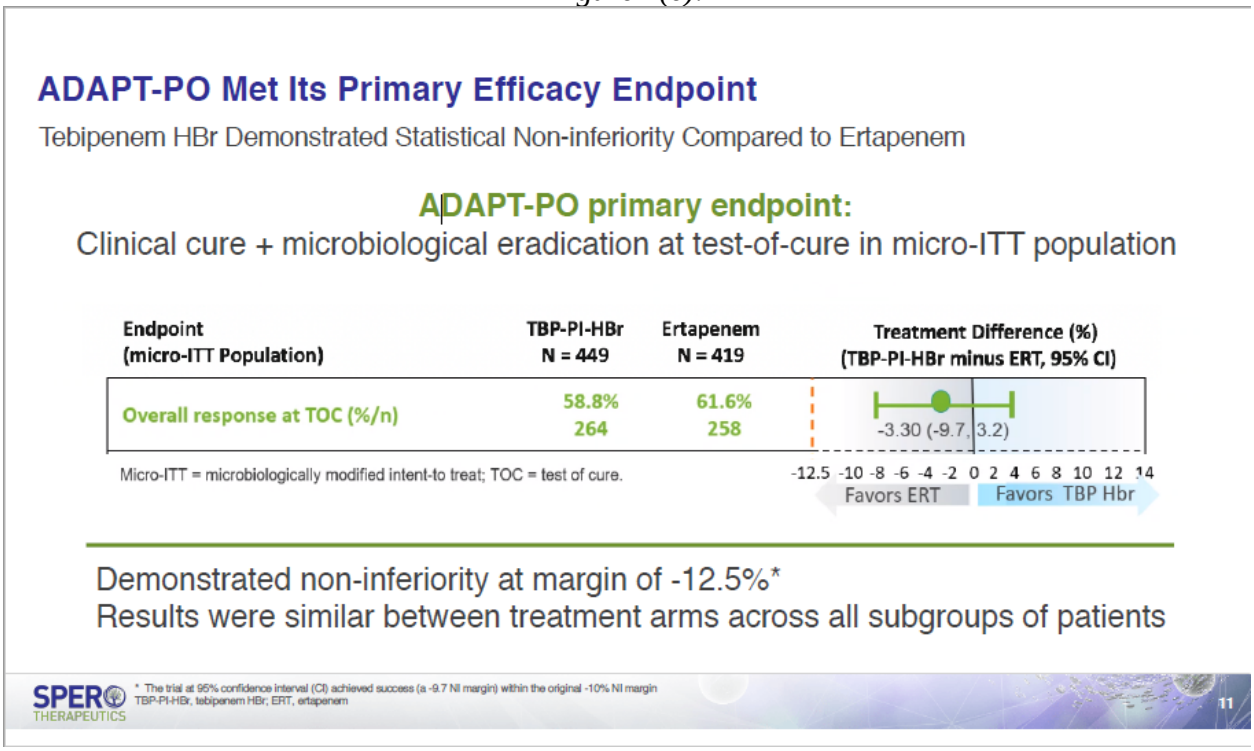
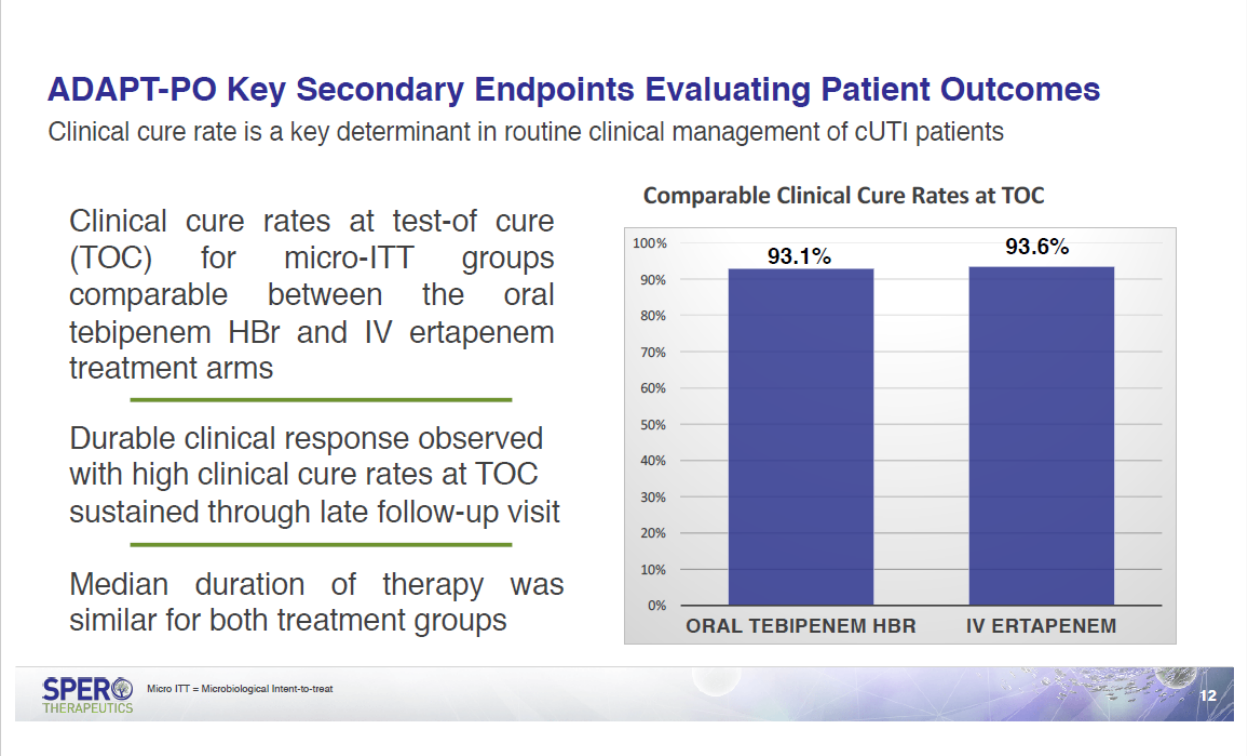


*Figure 7(c)*




90. The misrepresentations and omissions in the 3/16/2021 Oppenheimer Presentation and the 3/16/2021 Oppenheimer Slides as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

91. Defendants announced Spero's Q1 2021 quarterly results in a series of public statements on May 6, 2021, which discussed Spero's development of tebipenem HBr and its interactions with the FDA.

(a) On May 6, 2021, Spero issued an earnings press release (the "5/6/2021 Earnings Release"), which was filed with the SEC as an exhibit to a Form 8-K filed the same day (the "5/6/2021 Form 8-K") signed by Joseph, announcing its financial and operating results for the quarter ended March 31, 2021. On information and belief, given its discussion of the tebipenem HBr NDA and related communications with FDA and the fact that Defendant Mahadevia was quoted therein, the 5/6/2021 Earnings Release and 5/6/2021 Form 8-K were authorized and approved by the Individual Defendants. In it, Defendant Mahadevia is quoted as saying, "[w]e recently completed a pre-NDA meeting for tebipenem HBr with the FDA and ***received feedback indicating that the format and content of the planned data package we intend to include in our NDA will be sufficient to support the submission***. This regulatory milestone keeps us ***on track to submit the NDA in the second half of the year*** as we work to transition to a commercial-stage organization."

(b) Also on May 6, 2021, Defendants held an earnings call with analysts and investors in conjunction with Spero's Q1 2021 financial results (the "5/6/2021 Earnings Call"), on which Defendants Mahadevia and Shukla spoke. During prepared remarks, Defendant Mahadevia highlighted that "a ***major focus for Spero is the advancement of tebipenem HBr towards an NDA filing***." He continued by stating, ***"These efforts are supported by the positive Phase 3 ADAPT-PO trial results*** which we reported late last year. These results showed that the ***trial's primary endpoint was met with demonstrating that an all-oral regimen of tebipenem HBr is not inferior to an all-IV regimen of ertapenem for the treatment of complicated urinary tract infection or cUTI and acute pyelonephritis or AP***." His prepared remarks also emphasized Spero's interactions with the FDA regarding tebipenem HBr and the ADAPT-PO Trial by stating:

> ***Our previous FDA interactions and written communication indicated that positive results from the single well-controlled pivotal trials such as ADAPT-PO***

> ***could be sufficient to support the approval of a New Drug Application or NDA for tebipenem HBr in the treatment of cUTI and AP***.
>
> Today, I'm pleased to report that we recently ***completed a pre-NDA meeting with the agency*** and ***received feedback that was consistent with all of these prior interactions.*** The ***FDA has endorsed the structure and form of our planned NDA submission and indicated that the clinical data set and CMC plan that we intend to submit in the NDA package to meet their standards***.
>
> This ***positive regulatory interaction***, together with the fact that ***all of the data we need for submission is in our hand***s, keep us ***on track to complete the tebipenem HBr NDA submission in the second half of the year*** as we previously guided.

Defendant Mahadevia's prepared remarks also emphasized the safety and tolerability profile of tebipenem HBr by saying the following:

> Now, in addition to supporting NDA filing, another important goal of the ADAPT-PO trial was to answer the fundamental question that physicians and payers have regarding an oral version of a powerful IV medicine.
>
> And this question is if patients are going to receive oral therapy in place of an IV option, how does the safety and efficacy of the oral agent compare to the IV? We addressed this question by designing ADAPT-PO as the first head-to-head comparison of all-oral versus an all-IV regimen in cUTI.
>
> Specifically, we did not include an IV lead in the oral tebipenem HBr arm nor an oral step-down in the IV ertapenem arm as ***we wanted to provide physicians with direct evidence*** that we give them the confidence needed to prescribe tebipenem HBr to the millions of cUTI and AP patients who would otherwise receive IV therapy.
>
> As we have mentioned before, we believe we have done just now as our data show that ***tebipenem HBr can provide convenience of an oral therapy without any compromises on clinical response***, safety, or tolerability. And based on these compelling data, we believe tebipenem HBr if approved, would be an important treatment option for the over 2 million cUTI and AP patients in the US alone each year who are resistant to current available oral therapies.

During the Q&A portion of the call, Defendant Mahadevia discussed Spero's interaction with the FDA regarding the tebipenem HBr NDA, in this exchange:

> Analyst: … I guess in your pre-NDA meeting, did any either review issues or potential review issues arise? Other - were there any surprises I guess from your expectations going in or from your questions asked of the agency?

> Defendant Mahadevia: … In short Ritu, there were ***no surprises from the pre-NDA discussion***. And I reiterate the most important takeaways, which is on the basis of that meeting ***we're on track to submit the NDAs per our guidance in the second half of the year***. And that the ***FDA endorsed the structure and form of our planned submission and also the data set and the CMC plan that we've communicated publicly before***. So we're pleased with the outcome of that meeting.

When responding to an analyst question regarding how the COVID resource restraints that the FDA has experienced might impact the NDA submission, Defendant Mahadevia emphasized "the fact that ***we have a leg up and a head start in that the medicine that we've been developing has been on the market in Japan for 10 years, gives us a lot of confidence about the path forward***."

(c) On May 6, 2021, Spero filed a Form 10-Q with the SEC for Q1 2021 (the "Q1 2021 10-Q"), signed and SOX-certified by Defendants Mahadevia and Shukla. When describing the nature of Spero's business, Defendants touted tebipenem HBr as Spero's "most advanced product candidate" that is "designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections." Defendants also described Spero's pre-NDA meeting with the FDA on March 25, 2021 "to discuss format and content of the submission" which resulted in a "***consensus that the package as described would allow review of the NDA***." Thus, Defendants "***anticipate[d] submitting an NDA for tebipenem HBr to the FDA in the second half of 2021***."

92. The misrepresentations and omissions in the 5/6/2021 Earnings Release, 5/6/2021 Form 8-K, 5/6/2021 Earnings Call, and Q1 2021 10-Q, as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that

tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

93. On or about May 22, 2021, Spero personnel presented at the 2021 Making a Difference in Infectious Disease (MAD-ID) conference that was held May 20-22, 2021 (the "2021 MAD-ID Conference"). On information and belief, given that the 2021 MAD-ID Conference presentation and related materials addressed the ADAPT-PO Trial results and the tebipenem HBr NDA, they were authorized and approved by the Individual Defendants. Spero's website provided a link to materials presented at the conference.

(a) At the 2021 MAD-ID Conference, Spero presented slides titled "Oral Tebipenem is Non-Inferior to IV Ertapenem in Complicated Urinary Tract Infection (cUTI) and Acute Pyelonephritis (AP): Results From the Pivotal ADAPT-PO Study" that were previously presented at IDWeek 2020 (the "2021 MAD-ID Slides"). The 2021 MAD-ID Slides displayed the micro-ITT population in Figure 3(b) below and the percentages of micro-ITT patients broken down by gram-negative and gram-positive pathogens in Figure 4(b) below. They displayed the per-pathogen microbiological eradication at test-of-cure for the gram-negative pathogens (Enterobacterales), which was 63.0% in tebipenem HBr and 65.9% in ertapenem as shown in Figure 5(b) below. They concluded that based on the data from the micro-ITT population, "***ADAPT-PO Met the Primary Efficacy Endpoint***" and that "***Oral TBP-PI-HBr was non-inferior to IV ertapenem in overall response at TOC***" as shown in Figure 6(b) below. They touted the ADAPT-PO Trial's results by stating, "***Oral TBP-PI-HBr (600mg PO q8h) was non-inferior to ertapenem (1g IV q24h) in the treatment of hospitalized adult patients with cUTI/AP***," "***ADAPT-PO achieved all primary and secondary objectives***," and "***These effects were seen consistently***

***across patient subsets***." The 2021 MAD-ID Slides added, "***Spero expects that data from this single pivotal trial will support submission of an NDA***."

*Figure 3(b):*

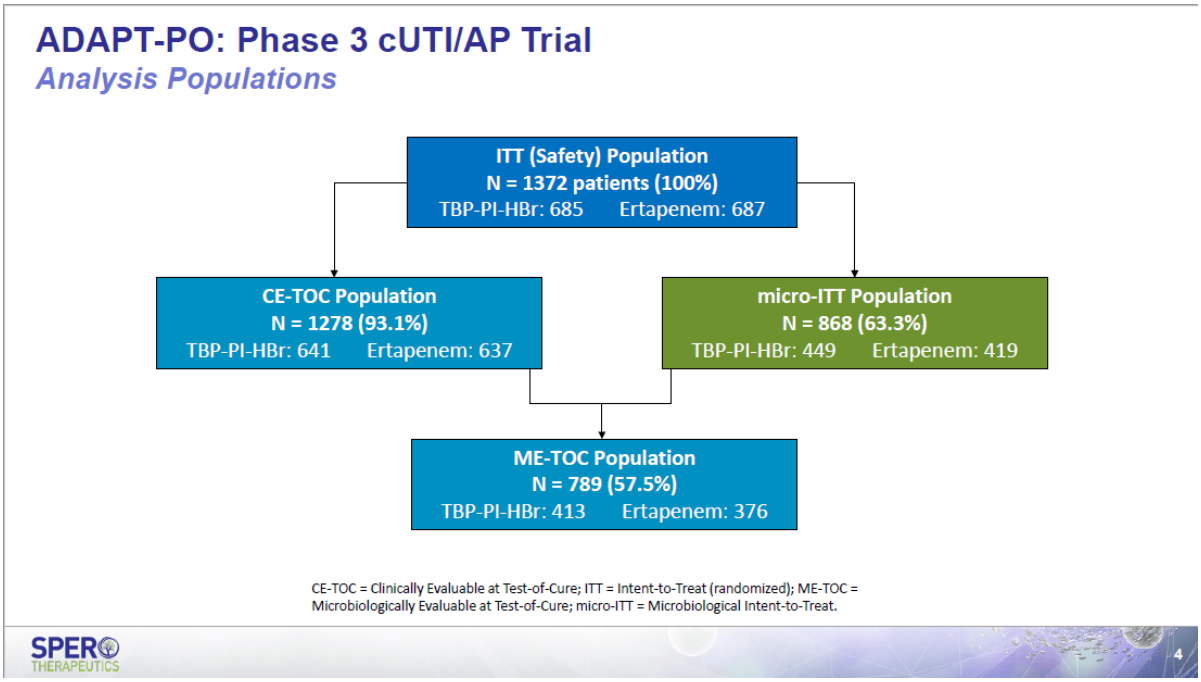



*Figure 4(b):*

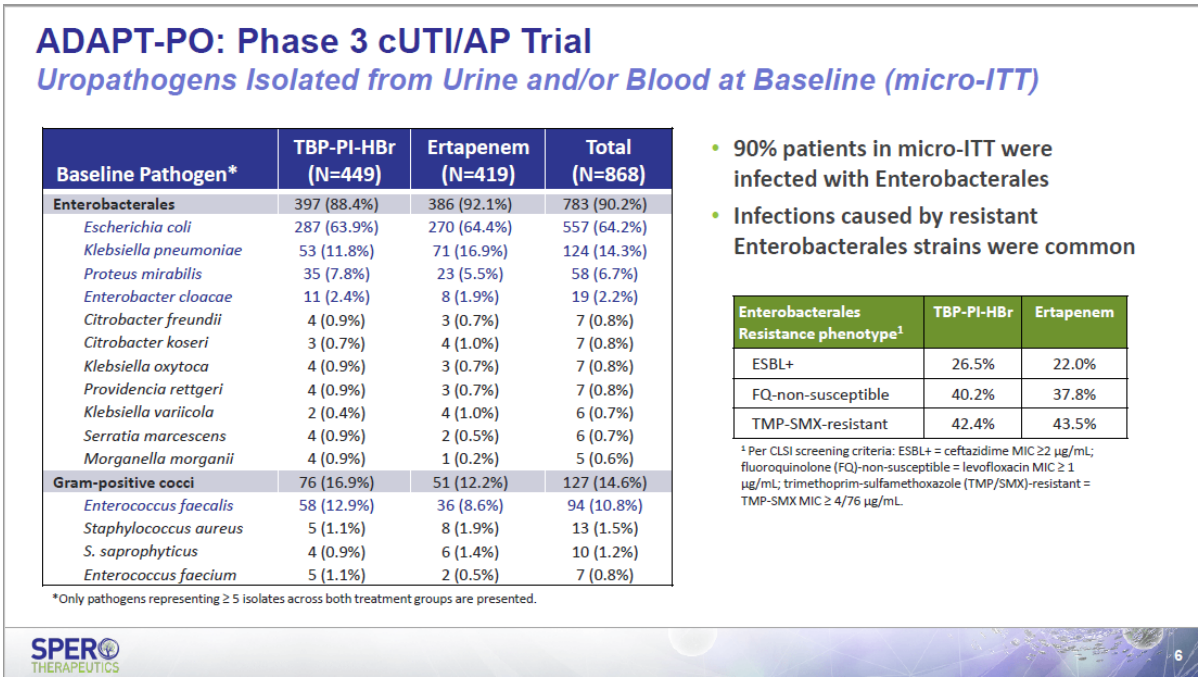


*Figure 5(b):*

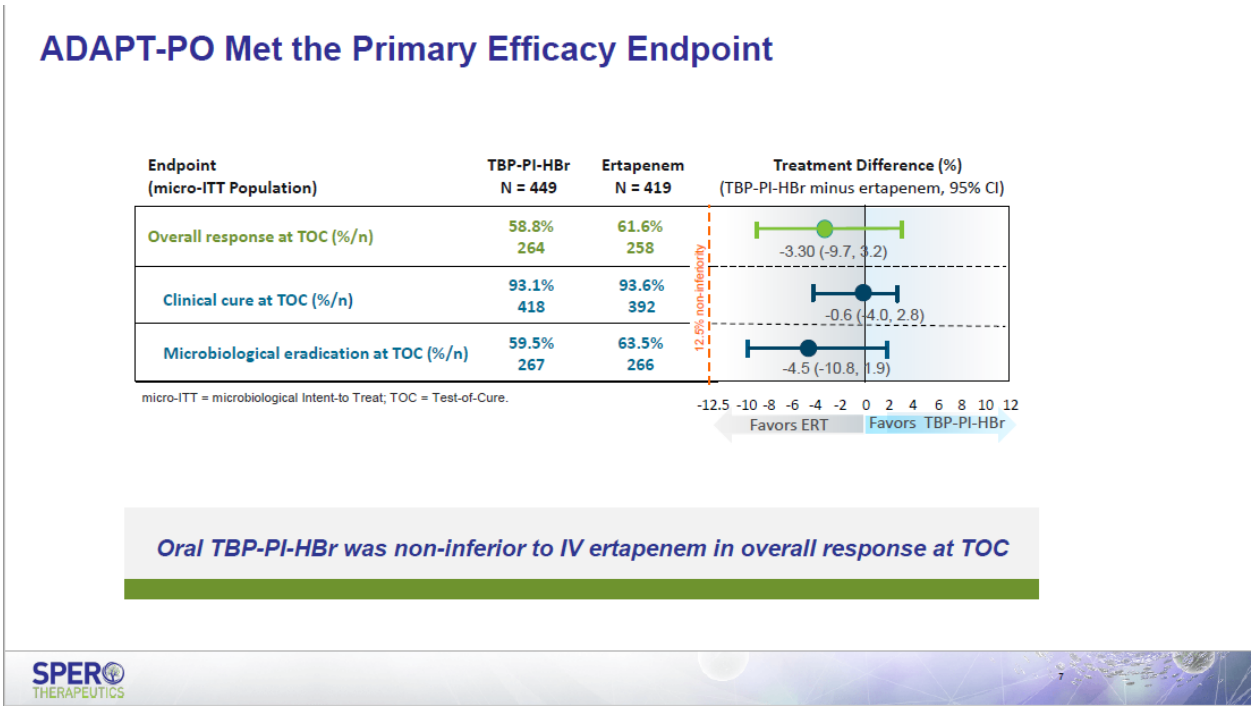
## ADAPT-PO: Phase 3 cUTI/AP Trial

### *Per-Pathogen Microbiological Eradication at TOC (micro-ITT)*

| Baseline Pathogen | TBP-PI-HBr N=449 % (n/N1) | Ertapenem N=419 % (n/N1) |
|---|---|---|
| **Enterobacterales*** | 320/508 (63.0%) | 337/511 (65.9%) |
| *E. coli* | 230/355 (64.8%) | 229/352 (65.1%) |
| *K. pneumoniae* | 35/65 (53.8%) | 52/78 (66.7%) |
| *P. mirabilis* | 23/42 (54.8%) | 21/31 (67.7%) |
| *E. cloacae* | 7/12 (58.3%) | 4/8 (50.0%) |
| **Resistant Enterobacterales Phenotypes** | | |
| ESBL+ | 57/105 (54.3%) | 53/85 (62.4%) |
| FQ-NS | 86/159 (54.1%) | 90/146 (61.6%) |
| TMP-SMX-R | 96/168 (57.1%) | 108/168 (64.3%) |

*Only pathogens with ≥ 5 isolates in either treatment group are presented.
ESBL+ = Expended-spectrum β-lactamase-producing; FQ-NS = fluoroquinolone-nonsusceptible; TMP-SMX-R = trimethoprim-sulfamethoxazole-resistant.

*Figure 6(b):*




(b) At the 2021 MAD-ID Conference, Spero personnel presented a poster titled, "Tebipenem: An Oral Carbapenem With Activity Against Multi-Drug Resistant Urinary Tract

Infection Isolates of *Escherichia Coli* Collected From US Medical Centers During 2019" (the "2021 MAD-ID Poster.") It assessed the activity of tebipenem HBr against E. Coli collected from UTIs in the U.S. and touted the ADAPT-PO Trial's results purporting to demonstrate the efficacy of tebipenem HBr compared to IV ertapenem stating, "***Tebipenem is an oral carbapenem that has recently demonstrated non-inferiority to IV ertapenem for the treatment of cUTI***" and "***Tebipenem represents a new oral option for cUTIs in an era of ESBL-mediated co-resistance to existing oral agents***."[11]

94. The misrepresentations and omissions made at the 2021 MAD-ID Conference, including in the 2021 MAD-ID Slides and 2021 MAD-ID poster, as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

95. On July 1, 2021, Spero filed with the SEC a Form 8-K (the "7/1/2021 Form 8-K"), signed by Joseph, announcing $40 million equity investment from Pfizer Inc. and licensing agreement for SPR206, another of Spero's drug candidates in phase 1 trials. The 7/1/2021 Form 8-K attached as Exhibit 99.1 a press release issued on June 30, 2021 (the "6/30/2021 Press Release"). Upon information and belief, given that they addressed the tebipenem HBr NDA and

[11] Here, "tebipenem" is used as a short-hand for tebipenem HBr as it references the purported ADAPT-PO Phase 3 study results for tebipenem HBr.

potential FDA approval and that they quoted Defendant Mahadevia, the 7/1/2021 Form 8-K and 6/30/2021 Press Release were authorized, approved, and written or edited by the Individual Defendants. The 6/30/2021 Press Release stated that "Spero intends to use the proceeds from the equity investment to prepare for the ***potential approval and launch of tebipenem HBr***." Defendant Mahadevia is quoted as stating, "***[t]he newly announced equity investment will provide us with valuable capital and financial flexibility as we [among other things,] work towards an NDA filing for tebipenem HBr***."

96. The misrepresentations and omissions in the 6/30/2021 Press Release, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

97. On July 13, 2021, Defendant Mahadevia gave a presentation at the Ladenburg Thalmann Healthcare Conference that took place July 13-14, 2021 (the "7/13/2021 Ladenburg Presentation"), as had been announced in a press release on July 7, 2021 (the "7/7/2021 Press Release"). During the conference, Defendant Mahadevia made a series of false and misleading statements and omissions.

(a) During prepared remarks at the 7/13/2021 Ladenburg Presentation, Defendant Mahadevia touted tebipenem HBr and the "landmark" ADAPT-PO Trial stating, "***it brings the power of IV therapy we've been using for patients for over a decade into pill form***,"

and "***in a first of its kind Phase III study[], oral tebipenem, demonstrated comparable efficacy and tolerability to the gold standard for complicated urinary tract infections, which is IV ertapenem***." He emphasized the testing rigor by stating "***Not only was it compared against an IV, but it was compared in a two-part test of signs and microbiological threshold, and it was compared after you waited 7 to 10 days after the last dose where the bugs might have had an opportunity to grow back***," and "***it had to be comparable where the data were tight enough that the lower bound of this confidence interval was [within 12.5% non-inferiority]***." He assured investors and analysts that "***we have the data in hand to submit our NDA***," "***[w]e expect completion of the NDA in the second half of the year***," and "Tebipenem has received fast-track designation, and that means an eight-month review timeline once we've submitted." Significantly, he confirmed that the data collected in the ADAPT-PO Trial was proper for approval based on meetings with the FDA stating, "***we've had a successful pre-NDA meeting with FDA***," "***[w]e've confirmed that the data we have in this one well-controlled pivotal trial is the data that's necessary for the approval of tebipenem***, and "we're looking forward to our continued collaborative dialogue with our colleagues at FDA." Defendant Mahadevia also gave a financial overview of Spero, driven, in large part, by funding for the ADAPT-PO Trial stating that cash position was $115 million as of the last quarter, not including the $40 million Pfizer transaction, and that Spero was funded into the second half of 2022, which includes the significant non-dilutive financing through BARDA/DTRA and NIH, among others.

(b) Also at the 7/13/2021 Ladenburg Presentation, Defendant Mahadevia presented a slide deck (the "7/13/2021 Ladenburg Slides"). The 2021 Ladenburg Slides touted the "landmark" ADAPT-PO Trial results as "***Robust***," and reiterated that the "***ADAPT-PO Met Primary Endpoint***," "***Overall combined response rate: Oral tebipenem HBr response rate of***

***58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin***)." They added, "Tebipenem HBr, as the first oral carbapenem, could allow ***appropriate patients*** the opportunity to receive treatment in the community setting." They also highlighted that "***Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem…at margin of -12.5%"*** based on analyses of the micro-ITT Population and that the "***Results were similar between treatment arms across all subgroups of patients***" as shown in Figure 1(f) below. They stated that "ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes: ***Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms***" as shown in Figure 7(d) below. They also reiterated that the NDA submission was on track, referring to the ADAPT-PO Trial as the "***One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions***" and stating, "***Positive ADAPT-PO Trial Results Support an NDA submission in 2H21***." They added, "***With the recently announced (6/30/2021) $40M transaction with Pfizer, Spero is funded into the second half of 2022***," ***"BARDA/DTRA non-dilutive funding award for tebipenem HBr up to $56.7M"*** with ***"additional awards and alliances provid[ing] funding for the pipeline,***" and that "***Tebipenem HBr Well Positioned to Recognize Significant Market Opportunity***."

*Figure 1(f):*

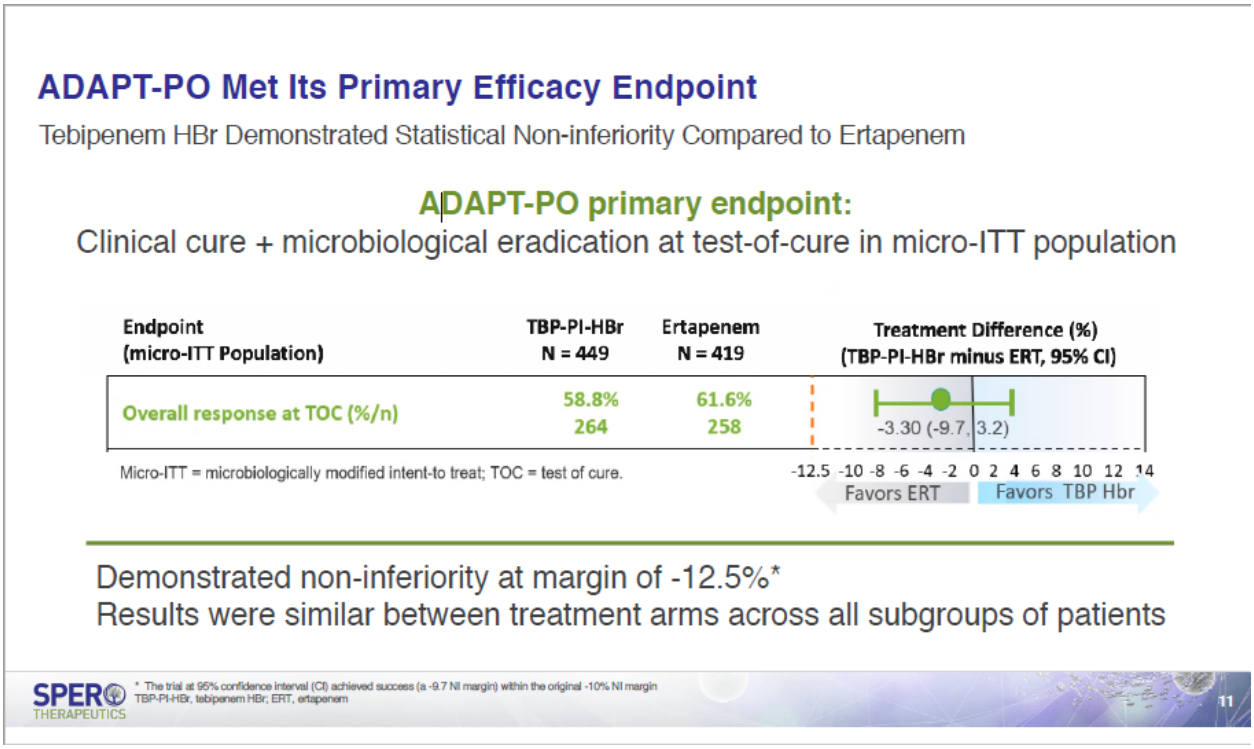
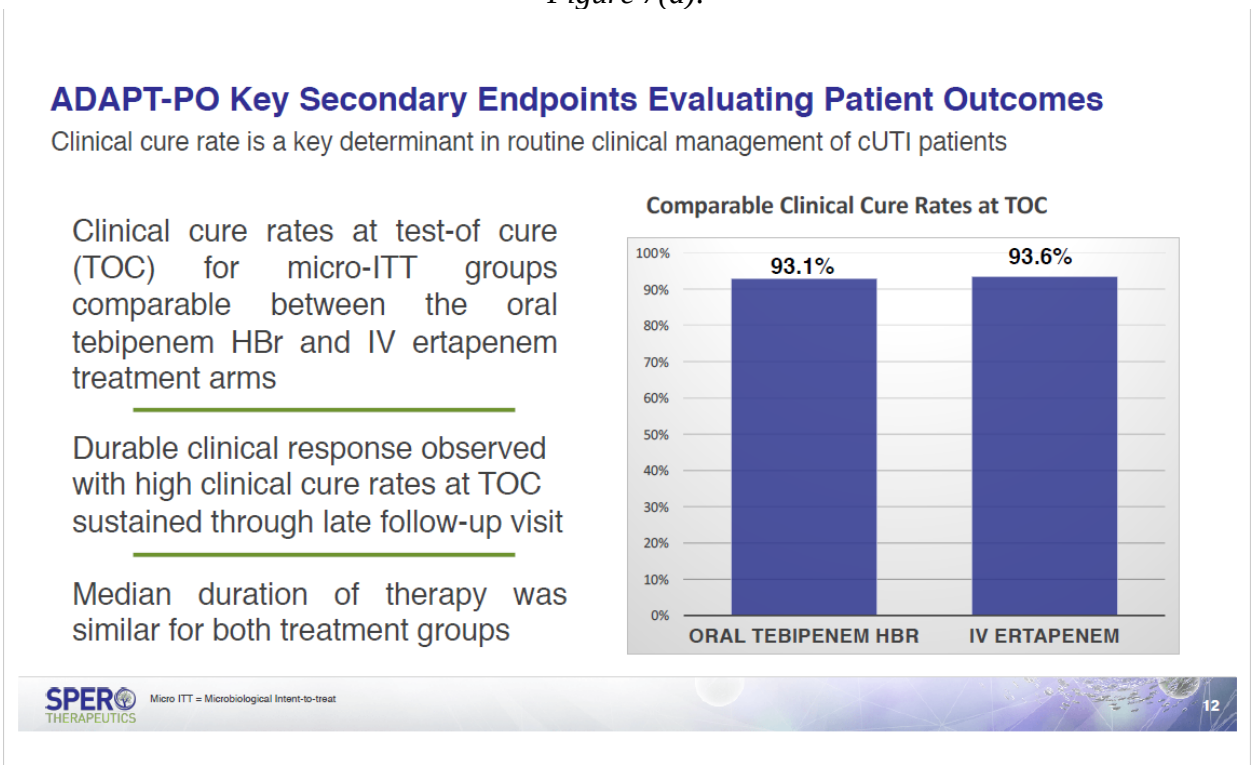



*Figure 7(d):*



98. The misrepresentations and omissions in the 7/13/2021 Ladenburg Presentation and 7/13/2021 Ladenburg Slides, as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

99. Also on July 13, 2021, Defendant Mahadevia was a guest on the Biotech 2050 Podcast (the "7/13/2021 Biotech 2050 Podcast"), during which he made false and misleading statements and omissions about tebipenem HBr and the ADAPT-PO Trial. He stated, "***[tebipenem HBr] has the same potency as an IV but it's in a pill form [a]nd, you know, we've been through a Phase 3 study which shows when you put it head-to-head against an IV carbapenem it does the job***." Defendant Mahadevia also assured investors that plans were on track for NDA submission stating, "***we're on the cusp now of filing for our FDA approval and looking to get that drug launched in the US.***"

100. The misrepresentations and omissions in the 7/13/2021 Biotech 2050 Podcast, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to

generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

101. Defendants announced Spero's Q2 2021 quarterly results in a series of public statements on August 5, 2021, which discussed Spero's development of tebipenem HBr and its upcoming NDA submission.

(a) On August 5, 2021, Spero issued an earnings press release (the "8/5/2021 Earnings Release"), which was filed with the SEC as an exhibit to a Form 8-K filed the same day (the "8/5/2021 Form 8-K") signed by Joseph, announcing its financial and operating results for the quarter ended June 30, 2021. Upon information and belief, given that they address the tebipenem HBr NDA and that they quote Defendant Mahadevia, the 8/5/2021 Earnings Release and 8/5/2021 Form 8-K were authorized, approved, and written or edited by the Individual Defendants. In the 8/5/2021 Earnings Release, Defendant Mahadevia is quoted as saying, "During the second quarter, we achieved ***key milestones which has us well positioned for future success, as we work to submit the tebipenem HBr NDA***, transition to a commercial organization, and advance our clinical-stage pipeline." He also emphasized that Spero's primary focus looking forward is to "***advance tebipenem HBr towards an NDA filing this year***, which moves [Spero] closer to providing an oral treatment for potentially millions of patients with complicated urinary tract infection."

(b) Also on August 5, 2021, Spero held an earnings call with analysts and investors in conjunction with its Q2 2021 financial results (the "8/5/2021 Earnings Call"), on which Defendants Mahadevia and Shukla spoke. During prepared remarks, Defendant Mahadevia highlighted that Spero "***remain[s] focused on preparing for the upcoming tebipenem HBr NDA filing***." He also discussed the NDA submission and positive ADAPT-PO Trial results:

> I'm pleased to say that our efforts around these interrelated goals have continued to advance on track. On our last call, we shared that ***we had accumulated all of the***

> ***data necessary for our NDA submission for tebipenem***. Since then, ***we have been performing all of the required analysis*** and drafting sections of the NDA, both at the study and summary levels. ***We've seen sustained progress on these fronts, and we're confident that we'll submit the NDA in the fourth quarter***. This is in line with the guidance provided on our last earnings call for an expected NDA submission during the second half of this year. ***Our efforts around tebipenem HBr are supported both by our strong clinical data and our positive regulatory interactions with FDA***.
>
> ***The positive Phase III ADAPT-PO trial results*** reported late last year showed that the ***trial's primary endpoint was met with data demonstrating that an all-oral regimen of tebipenem HBr is noninferior to an all-IV regimen of ertapenem for the treatment of complicated urinary tract infection, or cUTI, and acute pyelonephritis, or AP***.

His prepared remarks elaborated on Spero's interactions with the FDA and expressed confidence that tebipenem HBr would continue to advance as planned:

> Now our previous FDA interactions and written communication indicate that ***positive results from a single well-controlled pivotal trial such as ADAPT-PO could be sufficient to support the approval of an NDA for tebipenem HBr in the treatment of cUTI and AP***. Additionally, through feedback we received from our pre-NDA meeting, ***the FDA endorsed the structure and form of our planned NDA submission and indicated that the data set and CMC plan that we intend to submit in the NDA package meet their standards***.
>
> We are ***confident that our tebipenem HBr program will continue to advance its plan*** as we move through the second half of '21 and into 2022. Based on ***our positive clinical data and ADAPT-PO's rigorous design***, we believe that, if approved, tebipenem HBr will be an important physician treatment option for possibly over 2 million cUTI and AP patients in the U.S. alone who are resistant to currently available oral therapies.
>
> ADAPT-PO was designed as the first head-to-head comparison of an all-oral versus an all-IV regimen in cUTI specifically to provide a robust result that would give physicians confidence to prescribe tebipenem HBr to cUTI and AP patients, who would otherwise be required to receive IV therapy. We believe we have done just that as ***our data show that tebipenem HBr can provide the convenience of an oral therapy without any compromises on clinical response***, safety or tolerability.

When responding to an analyst question regarding medical education as it pertains to tebipenem HBr, Defendant Mahadevia said "we are developing data and publishing it that speaks to the value

that tebipenem brings to the health care system, and that is both for the clinicians who are very sensitive to these economics as well as our colleagues in the payer community."

(c) On August 5, 2021, Spero filed a Form 10-Q with the SEC for Q2 2021 (the "Q2 2021 10-Q"), signed and SOX-certified by Defendants Mahadevia and Shukla. In it, Defendants touted tebipenem HBr as Spero's "***most advanced product candidate***" that is "designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections." Additionally, it emphasized that "[t]reatment with effective orally administrable antibiotics may prevent hospitalizations for serious infections and enable earlier, more convenient and cost-effective treatment of patients after hospitalization." Defendants also stated that they were "***currently performing integrated analyses in conjunction with the NDA and drafting section of the NDA both at the study and summary level***" and "***anticipate the completion of an NDA submission to the FDA in the fourth quarter of 2021***."

102. The misrepresentations and omissions in the 8/5/2021 Earnings Release, 8/5/2021 Form 8-K, 8/5/2021 Earnings Call, and Q2 2021 10-Q, as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

103. On September 13, 2021, Spero COO Larkin gave a presentation at the H.C. Wainwright 23rd Annual Global Investment Conference that took place September 13-15, 2021

(the "9/13/2021 H.C. Wainwright Presentation"), as per a press release on September 7, 2021 (the "9/7/2021 Press Release"). On information and belief, given that the presentation covered the ADAPT-PO Trial results and tebipenem HBr NDA and that Defendant Mahadevia had been scheduled to participate per the 9/7/2021 Press Release, the 9/13/2021 H.C. Wainwright Presentation statements were authorized and approved by the Individual Defendants. During prepared remarks, Larkin touted tebipenem HBr and the "landmark" and "***successful***" ADAPT-PO Trial results stating, "***Now importantly, these results were similar across all the subgroups that we evaluated and successfully achieved the outcome of demonstrating the tebipenem oral achieved the similar outcome to IV ertapenem.***" Larkin emphasized the testing rigor, calling the ADAPT-PO Trial an "***important study design***," highlighting the multi-step test required by the FDA as "***the combination of this data [clinical cure and microbiological eradication] that measured patients' overall response and is the primary endpoint***," and bosting that "***we have successfully met the primary endpoint in meeting this non-inferiority to compare oral tebipenem to IV ertapenem, and the FDA NI-margin was set at a negative 12.5%...and we successfully cleared that hurdle of non-inferiority***." Larkin assured investors and analysts that Spero was on track to file an NDA for tebipenem HBr stating, "***We have successfully completed the single trial that's needed for U.S. approval and submitting our NDA in the fourth quarter***," and "Tebipenem has received Fast Track designation, which means that it will have an eight-month review once it's submitted." Specifically, Larkin confirmed that the data collected in the ADAPT-PO Trial was proper for approval based on meetings with the FDA stating, "***We've had a successful pre-NDA meeting with the FDA and confirm that the single trial is adequate to seek approval***."

104. The misrepresentations and omissions in the 9/13/2021 H.C. Wainwright Presentation, as alleged in the preceding paragraph, were materially false and misleading because,

as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

105. On September 16, 2021, Spero issued a press release (the "9/16/2021 Press Release") announcing that Spero would present data at the Infectious Disease Society of America (IDSA) IDWeek 2021 meeting held September 29 – October 3, 2021 ("ID Week 2021"), which provided a link to several presentation posters on Spero's website. On information and belief, the 9/16/2021 Press Release and the ID Week 2021 materials discussed below, given that they addressed the ADAPT-PO Trial results, were authorized and approved by the Individual Defendants.

(a) The 9/16/2021 Press Release provided a link to presentation poster (#1122) titled "Effect of Aluminum Hydroxide/Magnesium Hydroxide/Simethicone and Omeprazole on the Pharmacokinetics of Tebipenem Pivoxil Hydrobromide (TBP PI-HBr) in Healthy Adult Subjects" ("9/16/2021 IDWeek Poster 1122") that was presented during a session on September 29, 2021. It touted the ADAPT-PO Trial results, stating "***A completed Phase 3 study of patients with complicated urinary tract infection or acute pyelonephritis found that oral TBP-PI-HBr was non-inferior to intravenous ertapenem for clinical and microbiological response***."

(b) The 9/16/2021 Press Release provided a link to poster (#1120) titled "Absorption, Metabolism, and Excretion of [14C]-Tebipenem Pivoxil Hydrobromide (TBP-PI-

HBr) Following a Single Oral Dose in Healthy Male Subjects" ("9/16/2021 IDWeek Poster 1120") that was presented during a session on September 29, 2021. It referenced the purported positive results of the ADAPT-PO Trial stating "***Tebipenem pivoxil hydrobromide (TBP-PI-HBr) is an oral carbapenem with activity against multidrug-resistant gram-negative pathogens***."

106. The misrepresentations and omissions in the 9/16/2021 Press Release, 9/16/2021 IDWeek Poster 1122, and 9/16/2021 IDWeek Poster 1120 as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

107. On September 22, 2021, Defendant Mahadevia gave a presentation at the Oppenheimer Fall Healthcare Life Sciences & Med Tech Summit that took place September 20-23, 2021 (the "9/22/2021 Oppenheimer Presentation"), as had been announced in the 9/7/2021 Press Release. Defendant Mahadevia's prepared remarks touted tebipenem HBr and the "positive" ADAPT-PO Trial stating that the results "showed that our ***oral medicine is as efficacious*** and has similar safety profile ***to ertapenem.***" He emphasized the testing rigor and the multi-step test required by the FDA by stating that "patients not only have to feel better or show a clinical response, but they also have to show microbiological response," then the "***FDA requires patients to wait until 7 days -- 17 days to 21 days after their first dose***, in order to show that not only are we get clearing the bug but you're helping the bugs stay gone… and ***we're pleased to say that we***

***met that test***," "not only you have to be comparable, but that comparability [of] that data set has to be tight enough that you're above a certain difference threshold - ***that difference was agreed with FDA at minus 12.5% and we passed that with flying colors***," and "***we can say that tebipenem and ertapenem have comparable effects on this ill patient population***." He added, "***[Spero's] planning for NDA submission in the fourth quarter of 2021***," and "we have fast track which comes with an eight-month review cycle should the NDA be successfully accepted." Specifically, he confirmed that the ADAPT-PO Trial data was proper for approval based on meetings with the FDA, stating, "***[W]e know from our pre-NDA discussions and multiple FDA discussions prior to that one that this well-controlled pivotal trial will form the basis of an NDA submission***." When asked during Q&A to provide details about NDA timing, he confirmed Q4 2021 submission and reiterated that the ADAPT-PO Trial results were appropriate for the NDA filing. Stating that "***we have everything we need in hand to prepare and finalize the NDA submission***."

108. The misrepresentations and omissions in the 9/22/2021 Oppenheimer Presentation, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

109. On September 29, 2021, Defendant Mahadevia gave a presentation at the 2021 Cantor Virtual Global Healthcare Conference that took place September 27-30, 2021 (the "9/29/2021 Cantor Presentation"), as had been announced in the 9/7/2021 Press Release.

Defendant Mahadevia's prepare remarks touted tebipenem HBr and the "pivotal" ADAPT-PO Trial, stating that the results "***demonstrated that tebipenem had comparable efficacy to ertapenem.***" He emphasized the testing rigor and the multi-step test required by the FDA, stating that "patients need to feel better as per an FDA standard questionnaire" and "need to clear the microbes in their urine above a certain threshold," then "the FDA for their guidance has asked us to measure this response a week to 10 days after the patient has completed dosing." He said that "***the FDA puts one more hurdle on us in terms of showing that we have a successful trial***" which is that the tebipenem HBr meet the non-inferiority margin of -12.5%. He stated, "***Tebipenem cleared [the non-inferiority margin] with flying colors***" and he concluded, "***through an extremely stringent test, an all oral regimen of tebipenem was able to show that it could do the same thing for patients as IV ertapenem***." He confirmed Spero was on track to file an NDA for tebipenem HBr by stating, "***fourth quarter, we continue to expect our NDA submission***." He also confirmed that the data collected in the ADAPT-PO Trial was proper for approval based on meetings with the FDA, stating that "***through our multiple interactions with FDA, including a pre-NDA meeting, we know that one well controlled pivotal trial, that's ADAPT-PO, will perform the basis of an NDA submission"*** and "***[w]e have what we need in hand to complete that NDA submission***." He also gave a financial overview of Spero, stating, "***we're in a strong financial position***," [w]e are funded into the fourth quarter of 2022, including the Pfizer transaction," and "we've had an established track record of complementing equity with other sources [including] the $57 million grant that we signed with BARDA [t]hat's funded tebipenem and continues to help fund our investment in tebipenem." When an analyst asked during Q&A to provide information about international expansion opportunities, Defendant Mahadevia discussed the "step-wise approach" stating, "***[w]e are laser-focused on getting tebipenem approved in the US today***."

110. The misrepresentations and omissions in the 9/29/2021 Cantor Presentation, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

111. On October 28, 2021, Spero issued a press release (the "10/28/2021 Press Release") filed with the SEC the same day as Exhibit 99.1 to Form 8-K (the "10/28/2021 Form 8-K") signed by Joseph, announcing the submission of an NDA to the FDA for tebipenem HBr for the treatment of cUTI, including pyelonephritis. Upon information and belief, given that they addressed the ADAPT-PO Trial results and the interactions with FDA concerning the tebipenem HBr NDA and given that Defendant Mahadevia is quoted therein, the 10/28/2021 Press Release and 10/28/2021 Form 8-K were authorized, approved, and written or edited by the Individual Defendants. The 10/28/2021 Press Release touted the results of the ADAPT-PO Trial, stating, "***The NDA submission includes previously communicated positive data from the Phase 3 ADAPT-PO trial [which] showed that ADAPT-PO met its primary endpoint by demonstrating that oral tebipenem HBr was statistically non-inferior to IV ertapenem in the treatment of patients with cUTI and patients with acute pyelonephritis (AP).***" Defendant Mahadevia was quoted as stating,

> With the submission of this NDA, we have taken a major step towards potentially providing ***a substantial number of appropriate cUTI patients*** with an oral treatment option that could replace historical use of intravenous (IV) therapy … ***If approved, we believe tebipenem HBr could help patients significantly***, and the avoidance of IV administration could lead to reduced healthcare resource utilization. ***We look forward to working with the FDA during the NDA***

***review process as we prepare for tebipenem HBr's anticipated launch in the second half of 2022***.

112. The misrepresentations and omissions in the 10/28/2021 Press Release and the 10/28/2021 Form 8-K, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

113. Defendants announced Spero's Q3 2021 quarterly results in a series of public statements on November 10, 2021, which discussed Spero's development of tebipenem HBr and its recently submitted NDA.

(a) On November 10, 2021, Spero issued an earnings press release (the "11/10/2021 Earnings Release"), which was filed with the SEC as an exhibit to a Form 8-K filed the same day (the "11/10/2021 Form 8-K") signed by Joseph, announcing its financial and operating results for the quarter ended September 30, 2021. Upon information and belief, given that they addressed the tebipenem HBr NDA and that they quoted Defendant Mahadevia, the 11/10/2021 Earnings Release and 11/10/2021 Form 8-K were authorized, approved, and written or edited by the Individual Defendants. In the 11/10/2021 Earnings Release, Defendant Mahadevia was quoted as saying that chief among Spero's quarterly accomplishments "was our ***recent NDA submission for tebipenem HBr, which, if approved, would make it the first oral carbapenem antibiotic available for use in cUTI***." He also said that Spero "entered into a revenue interest

financing agreement with HealthCare Royalty Partners, providing [it] with non-dilutive capital to support tebipenem's anticipated launch."

(b) Also on November 10, 2021, Spero held an earnings call with analysts and investors in conjunction with its Q3 2021 financial results (the "11/10/2021 Earnings Call"), on which Defendants Mahadevia and Shukla spoke. Defendant Mahadevia's prepared remarks highlighted that "***Spero's primary focus remains on preparing for an anticipated tebipenem HBr commercial launch in the second half of 2022***" and that "I'm pleased to say that, over the past months, ***we've achieved key milestones to advance our efforts towards this important goal***." He also highlighted tebipenem HBr "milestones" and purported progress by saying:

> ***Chief among these milestones was our recent submission of an NDA package***, seeking approval for tebipenem HBr tablets for the treatment of complicated urinary tract infections, including pyelonephritis caused by susceptible microorganisms. ***A key part of this NDA package is the positive data set from our Phase III ADAPT-PO clinical trial***. These data showed that ***ADAPT-PO met its primary endpoint by demonstrating within an all-oral regimen of tebipenem HBr, was non-inferior to an all-IV regimen of ertapenem for the treatment of complicated urinary tract infection or cUTI and acute pyelonephritis or AP***.
>
> ***Previous FDA interactions and written communications support our efforts to advance tebipenem HBr towards commercialization***. They indicate the ***positive results from single well-controlled pivotal trials such as ADAPT-PO, could be sufficient to support the approval of an NDA for tebipenem HBr in the treatment of cUTI, including pyelonephritis***.
>
> Further, through a pre-NDA meeting, the ***FDA also previously endorsed the structure in the form of our recent NDA submission***. The ***agency indicated that, the data set and CMC plan that are now included in the package meet FDA submission standards***. Given our submission date of 27 October, we anticipate that, if FDA's initial two-month review during this filing period is successful, the formal NDA review clock will start at the end of the year with a PDUFA date six months from that point or in mid-2022.

Defendant Mahadevia's prepared remarks also touted the ADAPT-PO Trial's design:

> In addition to supporting our NDA submission, another key goal of the ADAPT-PO trial was to provide physicians with the confidence needed to prescribe oral tebipenem HBr to cUTI patients who would otherwise receive IV therapy. We

> therefore designed ADAPT-PO as the first ever head-to-head comparison of an all-oral versus an all-IV regimen in cUTI. Thanks to ***this rigorous design***, we believe we have achieved our goal as data show that ***tebipenem HBr can provide the convenience of an oral therapy without making compromises on clinical response***, safety or tolerability.

When responding to an analyst question regarding the utility of tebipenem outside of treating cUTI, Defendant Mahadevia emphasized that "***we went head-to-head against ertapenem***" and that "***there are many uses of ertapenem outside of cUTI***."

(c) November 10, 2021, Spero filed a Form 10-Q with the SEC for Q3 2021 (the "Q3 2021 10-Q"), signed and SOX-certified by Defendants Mahadevia and Shukla. When describing the nature of its business, Spero touted tebipenem HBR as Spero's "most advanced product candidate" that is "***designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections.***" and reported that it had submitted an NDA to the FDA for tebipenem HBr tablets. It also emphasized that "[t]reatment with effective orally administrable antibiotics may prevent hospitalizations for serious infections and enable earlier, more convenient and cost-effective treatment of patients after hospitalization." Additionally, Spero reported that it had submitted an NDA to the FDA "for tebipenem HBr tablets for the treatment of complicated urinary tract infections, including pyelonephritis, caused by susceptible microorganisms."

114. The misrepresentations and omissions in the 11/10/2021 Earnings Release, 11/10/2021 Form 8-K, 11/10/2021 Earnings Call, and Q3 2021 10-Q, as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO

Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

115. On November 24, 2021, Defendant Mahadevia gave a presentation at the Piper Sandler 33rd Annual Virtual Healthcare Conference that took place November 29 – December 2, 2021 (the "11/24/2021 Piper Sandler Presentation"), as had been announced in a press release on November 17, 2021 (the "11/17/2021 Press Release"). Defendant Mahadevia's prepared remarks discussed the patient population of the ADAPT-PO Trial only in terms of the total number of patients enrolled as opposed to the results broken down into the micro-ITT population stating, "***we randomized a fairly large patient set, almost 1,350 patients, one to one and patients either got all oral tebipenem or all-IV ertapenem***." He touted tebipenem HBr, the "landmark" and "pivotal" ADAPT-PO Trial and its "positive results," stating, ***"[tebipenem HBr] passed a very tough test***." He emphasized testing rigor and the multi-step test required by the FDA by stating that "***we've set tebipenem for stringent test,*** all oral against all the IV. It has to meet that two-part test, feel better and clearer urine and you have to wait time after the medicine is done being dosed [7-10 days] before you can measure it." He added, "***[T]he FDA also requires that data set is fairly tight***" [a]nd "***so they set a non-inferiority margin where the lower bound of that confidence interval in the left hand side cannot cross minus 12.5%."*** He concluded, "***[W]ith all of that our oral regimen compared well to ertapenem in the statistical test [a]nd we can say that tebipenem and ertapenem drive comparable outcomes in a fairly ill patient population with cUTI.***" He continued, "[W]e do have fast track designation from FDA [a]nd if our application completes that review phase, which could take two months after our submission, we will begin a six-month review phase for the application." He confirmed that the ADAPT-PO Trial data was proper for FDA approval based

on meetings with the FDA, stating, "***[W]e know from multiple FDA interactions as well as a pre-NDA meeting, that the ADAPT-PO trial is sufficient for the basis of an NDA submission"*** and ***[w]e've made that submission."*** He also gave a financial overview of Spero that included the Revenue Interest Agreement to bring tebipenem to market, stating, "[W]e've signed a ***revenue interest financing agreement [extending] our cash runway [] into the second half of '23*** [and we're] ***investing that to be able to bring tebipenem in the pipeline to market***."

116. The misrepresentations and omissions in the 11/24/2021 Piper Sandler Presentation, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

117. On December 1, 2021, Defendant Mahadevia spoke at the 4th Annual Evercore ISI HealthCONx Conference that took place November 30 – December 2, 2021 (the "12/1/2021 Evercore Presentation"), as had been announced in the 11/17/2021 Press Release. During the Q&A, in response to an analyst question regarding the possibility of an FDA advisory committee meeting about the NDA submission, he said that Defendants were not aware of any issues that would necessitate an advisory committee review.

> Analyst: So are we expecting an advisory committee meeting review of tebipenem? What issues, if any, are there to really just us for reviewing for label.

> Mahadevia: [ ] And so ***as we look at the data set and reflect on our pre-NDA discussions and our many discussions before that, we are not asking for anything that's outside of the guidance. We are going right down the fairway both with the ADAPT-PO trial design as well as what we're asking for on the basis of it.*** So we wouldn't -- ***we can't think of a particular issue that would drive an [Advisory Committee].*** We will say that sometimes the FDA uses [Advisory Committees] to showcase a particular medicine or approval pathway. We've seen that in our field. So that would be the only reason we could think of why it might happen, ***but not for a kind of answering a policy question this year.***

In response to an analyst question about cUTI patient populations, Defendant Mahadevia said, "***[T]he patient population that we can serve with the medicine is quite large [a]nd we've used multiple triangulating sources of data to help us understand that [including] with ertapenem the comparator in the ADAPT-PO's trial usage in cUTI***."

118. The misrepresentations and omissions in the 12/1/2021 Evercore Presentation, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

119. On January 3, 2022, Spero issued a press release (the "1/3/2022 Press Release") filed with the SEC on January 4, 2022 as Exhibit 99.1 to Form 8-K (the "1/4/2022 Form 8-K") signed by Joseph. Upon information and belief, given that they addressed the tebipenem HBr NDA and quoted Defendant Mahadevia, the 1/3/2022 Press Release and 1/4/2022 Form 8-K were authorized, approved, and written or edited by the Individual Defendants. The 1/3/2022 Press Release announced that the ***FDA "granted Priority Review designation and confirmed the***

***acceptance for substantive review of the New Drug Application (NDA) seeking approval for tebipenem HBr oral tablets for the treatment in adult patients with complicated urinary tract infections (cUTI), including acute pyelonephritis, caused by susceptible microorganisms***." It also stated that "tebipenem HBr has been granted Qualified Infectious Disease Product (QIDP), Fast Track, and Priority Review designations for these cUTI indications" and that ***the FDA "is planning to hold an Advisory Committee meeting to discuss [the NDA] and has also set a Prescription Drug User Fee Act (PDUFA) target action date of June 27, 2022***." It added, "***ADAPT-PO was rigorously designed both to support this NDA*** and to provide physicians with the confidence needed to prescribe oral tebipenem HBr to ***appropriate patients*** in place of IV therapy, if approved" and "***[w]e believe the positive results from the trial have allowed us to accomplish this first goal*** and indicate that ***use of tebipenem HBr may ultimately improve patient care***" in cUTI. Defendant Mahadevia was quoted as touting this "***important accomplishment***" and said, ***"The FDA acceptance of this NDA is a major step forward in our mission to provide patients the first and only oral carbapenem antibiotic to treat cUTI***" and ***"[w]e are committed to working closely with the FDA throughout the NDA review process and look forward to tebipenem HBr's anticipated launch in the second half of 2022***."

120. The misrepresentations and omissions in the 1/3/2022 Press Release and 1/4/2022 Form 8-K, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-

specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

121. On January 19, 2022, Spero issued a press release (the "1/19/2022 Press Release") filed with the SEC the same day as Exhibit 99.1 to Form 8-K (the "1/19/2022 Form 8-K") signed by Joseph. Upon information and belief, given that they addressed the ADAPT-PO Trial and tebipenem HBr NDA and that they quoted Defendant Mahadevia, the 1/19/2022 Press Release and 1/19/3033 Form 8-K were authorized, approved, and written or edited by the Individual Defendants. The 1/19/2022 Press Release announced that Spero and BARDA expanded their existing partnership to develop tebipenem HBr as a treatment for cUTI, including pyelonephritis, in pediatric patients. It stated that BARDA added and exercised a new option on the contract originally awarded to Spero in 2018, increasing the amount of committed funding by $12.9 million to $46.9 million, thereby increasing the total potential contract value to $59.7 million. Defendant Mahadevia again touted the purported strength of the ADAPT-PO Trial data, stating that the new option "***provides further external validation for tebipenem HBr and its robust clinical dataset***." The 1/19/2022 Press Release also reiterated that the ***"[NDA] seeking approval for tebipenem HBr oral tablets for treatment in adult patients with cUTI, including pyelonephritis, caused by susceptible microorganisms, [is] under review by the United States Food and Drug Administration.***"

122. The misrepresentations and omissions in the 1/19/2022 Press Release, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the

ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

123. On January 25, 2022, Spero filed with the SEC an updated investor presentation titled "January 2022 Spero Therapeutics Corporate Presentation" (the "1/25/2022 Presentation Slides") as Exhibit 99.1 to a Form 8-K filed the same day (the "1/25/2022 Form 8-K") and signed by Joseph, which said that the slides would be used in general corporate presentations, made available on Spero's website, and distributed by Spero in hardcopy or electronic form. On information and belief, given that they discuss the ADAPT-PO Trial results and interactions with the FDA concerning the tebipenem HBr NDA, the 1/25/2022 Form 8-K and 1/25/2022 Presentation Slides were authorized and approved by the Individual Defendants. The 1/25/2022 Presentation Slides touted the "landmark" ADAPT-PO Trial results as "***Robust***," and reiterated that "***ADAPT-PO Phase 3 met its primary endpoint in landmark trial – Oral tebipenem HBr demonstrated noninferiority to IV ertapenem in cUTI and AP, Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin***)." They added, "Tebipenem HBr, if approved as the first oral carbapenem, could allow ***appropriate patients*** the opportunity to receive treatment in the community setting." The 1/25/2022 Presentation Slides also highlighted that "***Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem…at margin of -12.5%"*** based on analyses of the micro-ITT population and that the "***Results were similar between treatment arms across all subgroups of patients***" as shown in Figure 1(g) below. They stated that "ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes: ***Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms***" as

shown in Figure 7(e) below. They reiterated that the NDA submission was still on course for review and possible approval and referred to the ADAPT-PO Trial as the "***One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions***," and said that "***Positive ADAPT-PO Trial Results Support an accepted NDA submission…with Priority Review, PDUFA Date: June 27, 2022.***" They added that Spero was "***HCR Revenue Interest Funding (9/30/2021): $50M upfront in October 2021 plus $50M upon FDA approval of tebipenem HBr, extends cash runway into 2H 2023***," ***"BARDA/DTRA non-dilutive funding award for tebipenem HBr up to $69.7M"*** with ***"additional awards and alliances provid[ing] funding for the pipeline,***" and that "***Tebipenem HBr Well Positioned to Recognize Significant Market Opportunity***."

*Figure 1(g):*

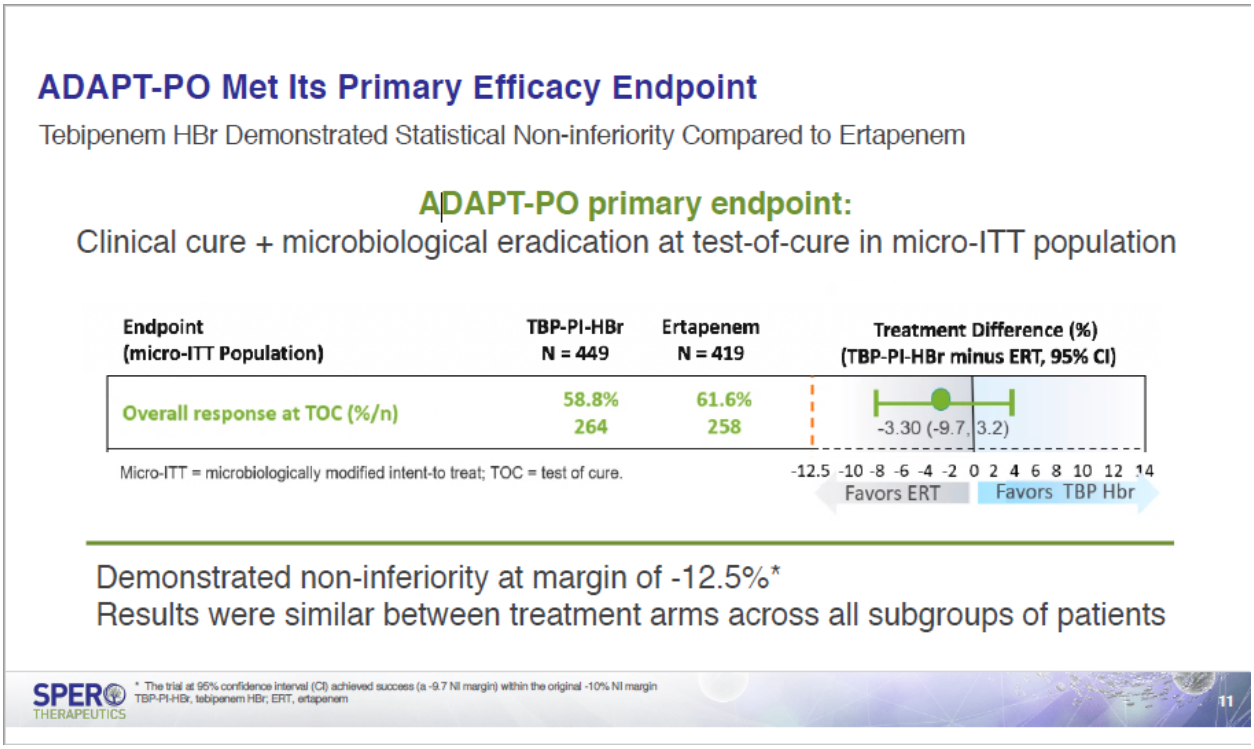
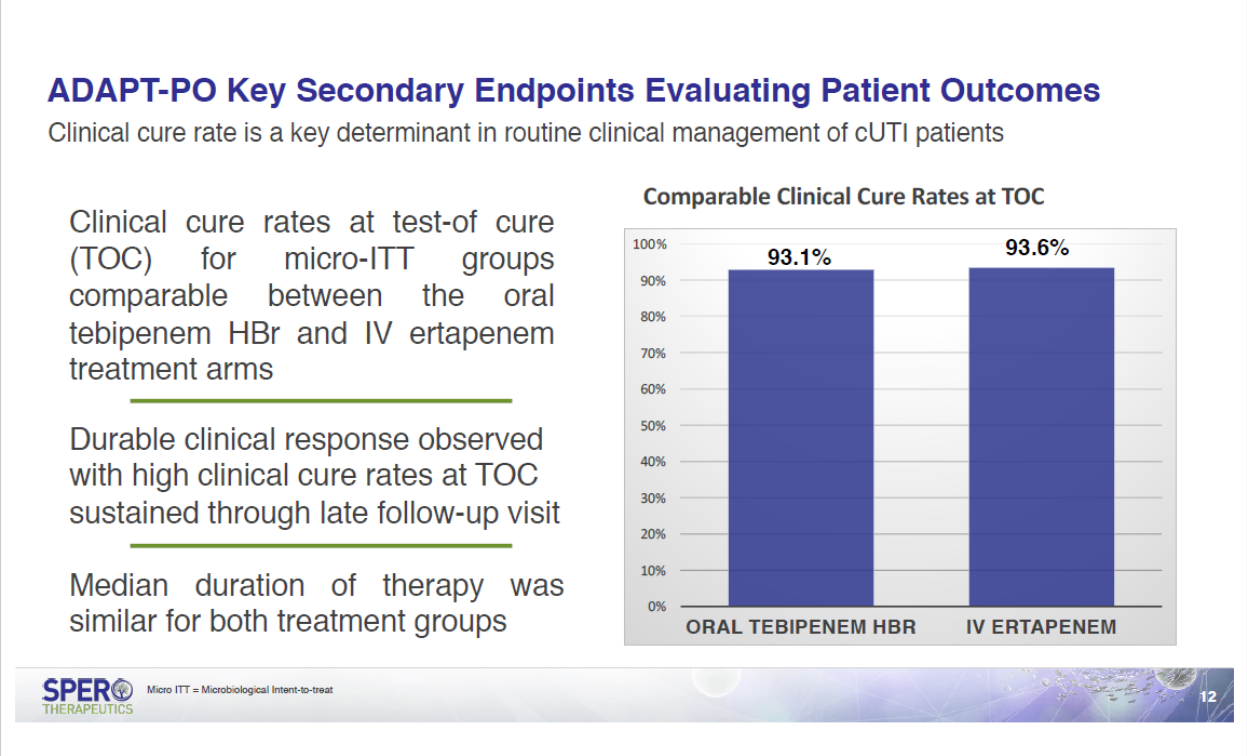


*Figure 7(e):*




124. The misrepresentations and omissions in the 1/25/2022 Presentation Slides, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

125. Defendants announced Spero's Q4 2021 quarterly and full year 2021 results in a series of public statements on March 31, 2022, which discussed Spero's development of tebipenem HBr and interaction with the FDA regarding its NDA. Defendants' public statements were

intended to mute the corrective effects of negative news and correlating stock price drop, as discussed in the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*.

(a) On March 31, 2022, Spero issued an earnings press release (the "3/31/2022 Earnings Release"), which was filed with the SEC as an exhibit to a Form 8-K (the "3/31/2022 Form 8-K") signed by Joseph, announcing its financial and operating results for the quarter and year ended December 31, 2021. On information and belief, given that they addressed the interactions with the FDA concerning the tebipenem HBr NDA and that they quoted Defendant Mahadevia, the 3/31/2022 Earnings Release and 3/31/2022 Form 8-K were authorized, approved, and written or edited by the Individual Defendants. In the 3/31/2022 Earnings Release, Defendant Mahadevia was quoted as saying that despite the FDA's identifying deficiencies in the tebipenem HBr NDA, as discussed in the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, "***we believe there would be sufficient time to progress to labeling discussions within the existing PDUFA timeframe***" and that ***"[w]e continue to prepare for an anticipated launch of tebipenem HBr in the second half of 2022, as we work with the FDA***."

(b) Also on March 31, 2022, Spero held an earnings call with analysts and investors in conjunction with its Q4 2021 and full year 2021 financial results (the "3/31/2022 Earnings Call"), on which Defendants Mahadevia and Shukla spoke. Defendant Mahadevia's prepared remarks stated that, despite the FDA's identifying deficiencies in its NDA, as discussed in the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, Defendants "***continue to have an active dialogue with FDA, and we'll continue to collaborate with them on the best path forward for tebipenem as quickly as we can***. If this can be done to the FDA['s] satisfaction, we believe there would be sufficient [time] to progress labeling anti-PMC PMR discussions within the existing PDUFA time frame, given how early in the review

period those discussions were originally scheduled to occur." He added that Spero "***continue[s] to believe in the strength of our application***" and that the "***foundation of that is our previously announced data from the Phase 3 ADAPT-PO trial***." He also touted the ADAPT-PO Trial and the anticipated publication of its results, saying:

> These data showed the ***trial meeting its primary endpoint as specified in the protocol by demonstrating that oral tebipenem HBr was statistically noninferior to intravenous tebipenem in the treatment of patients with complicated urinary tract infections or cUTI, and patients with acute pyelonephritis or AP***.
>
> We are expecting the publication of the ADAPT-PO trial results in a high-impact peer review journal in early Q2. ADAPT-PO was designed as the first head-to-head comparison of an oral versus IV regimen in cUTI. We believe it shows that ***tebipenem can provide the benefits of an oral therapy without making any compromises on clinical response***, safety or tolerability. We believe ***data from the trial*** not only ***supports our NDA***, but if approved by the FDA, will potentially provide physicians with the confidence needed to prescribe oral tebipenem HBr to appropriate patients in the place of IV therapy.

In response to an analyst question regarding communications with the FDA about deficiencies identified in the tebipenem HBr NDA, Defendant Mahadevia emphasized that Defendants "***continue to have a frequent and active interaction with our colleagues at the FDA***" and "***continue to engage with them on a variety of subjects within the NDA application as the process has gone on***." In response to the analyst's follow-up question, he said that Defendants have "***engagement with the agency on a variety of topics***" and "***engaged with them real time***." In response to a second follow-up question, Defendant Mahadevia said that Defendants "***had a very productive and collaborative engagement with FDA, where we continue to correspond with them on the basis of the data that we've submitted***." Additionally, during the Q&A portion of the call, Defendant Mahadevia discussed the status of the tebipenem HBr review:

> Analyst: So first question is what typically occurs during a late-cycle review just generally? And then is that where at some point? And how would that shift in terms of where your discussions are with the FDA?

> Defendant Mahadevia: … I think one point that you're alluding to is that our PDUFA date is in late June, and we're sitting here in late March. We are about halfway through the planned review period. And you make an important point that that late cycle review meeting is another opportunity for us to engage with the agency on the topics that we've continued to be engaging with them on during the review period.
>
> So what I want to emphasize from our prior remarks is that we are in a ***deliberative and collaborative phase with our colleagues and agencies***, not in a decisional phase and that continued dialogue including the late cycle visit gives us an opportunity to continue to ***work with them collaboratively to find the right path forward***.

(c) On March 31, 2022, Spero filed a Form 10-K with the SEC for Q4 2021 and year end 2021 (the "2021 10-K"), signed and SOX-certified by Defendants Mahadevia and Shukla. When describing the nature of Spero's business, Defendants labeled tebipenem HBR as its "most advanced product candidate" and touted several "***key attributes***" that "***support our confidence in tebipenem HBr's commercial potential***." Defendants also expressed their belief that "tebipenem HBr, if successfully developed and approved, would have a meaningful patient impact and significant commercial applications for the treatment of certain bacterial infections that cause cUTI in both the community and hospital settings" and that, "[i]n addition to cUTI, … tebipenem HBr has the potential to treat other serious and life-threatening infections." Additionally, Defendants touted tebipenem HBr's safety and efficacy profile as having "the potential to be a safe and effective treatment for cUTI," given the "***positive topline data results from ADAPT-PO, the pivotal Phase 3 clinical trial evaluating … tebipenem HBr***" which "***achieved its primary objective***, as specified in the protocol, ***demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous ertapenem in the treatment of patients with cUTI and patients with AP*** with respect to the primary endpoint of overall response at the test-of-cure ('TOC') visit in the microbiological-intent-to-treat ('ITT') ('micro-ITT') population." Defendants also expressed intent "to work with the FDA to seek to resolve the deficiencies expeditiously. Defendants

continued that "[i]f this can be done to the satisfaction of the FDA, we believe there would be sufficient time to progress to labeling discussions within the existing PDUFA timeframe, given how early in the review period those discussions were originally scheduled to occur." Defendants added that they "***continue to prepare for an anticipated commercial launch of tebipenem HBr in the second half of 2022, as we work with the FDA***."

126. The misrepresentations and omissions in the 3/31/2022 Earnings Release, 3/31/2022 Form 8-K, 3/31/2022 Earnings Call, and 2021 10-K, as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

127. On April 6-7, 2022, Defendants made a series of false and misleading statements regarding the results of the ADAPT-PO Trial and the status of the tebipenem HBr NDA.

(a) On April 6, 2022, Spero issued a press release (the "4/6/2022 Press Release"), which was filed with the SEC on April 7, 2022 as Exhibit 99.1 to Form 8-K (the "4/7/2022 Form 8-K") signed by Joseph, announcing publication in *The New England Journal of Medicine* (NEJM) of the results from the ADAPT-PO Trial. On information and belief, given that they addressed the ADAPT-PO Trial and tebipenem HBr NDA, the 4/6/2022 Press Release and 4/7/2022 Form 8-K were authorized and approved by the Individual Defendants. The 4/6/2022 Press Release called the trial "landmark" as "the first Phase 3 head-to-head comparison of an all-

oral versus all-IV treatment regimen in cUTI or acute pyelonephritis." It stated that Spero "***seeks approval for tebipenem HBr for the treatment of cUTI, including pyelonephritis, caused by certain microorganisms, in adult patients who have limited oral treatment options***" and "***included the results from the completed Phase 3 trial in the NDA filed with the FDA***." It affirmed that tebipenem HBr remained on track for possible approval stating, "***[T]he FDA accepted the NDA for substantive review***, granted Priority Review designation, and the FDA has assigned a PDUFA target date of June 27, 2022."

(b) The 4/6/2022 Press Release provided a link to the paper published on April 7, 2022 in the NEJM, titled, "Oral Tebipenem Pivoxil Hydrobromide in Complicated Urinary Tract Infection" (the "4/7/2022 NEJM Publication"). It stated that tebipenem HBr is "***an orally bioavailable carbapenem with activity against***" "***multi-drug resistant gram-negative pathogens***" such as those that cause cUTI and acute pyelonephritis. It described the evaluable population, stating, "***The intention-to-treat population included all the patients who underwent randomization***" and had "***confirmed diagnosis of complicated urinary tract infection or acute pyelonephritis and a positive urine culture at baseline***" while the "safety population included all the patients who received at least one dose of a trial drug." It described the "***microbiologically evaluable population [as comprising] patients who were included in both the microbiologic intention-to-treat population and the clinically evaluable population***." It broke down patient population further as shown in Figure 8 below. The 4/7/2022 NEJM Publication stated, that "we ***calculated that enrollment of approximately 1200 patients up to a maximum of 1450 (contingent on the number of evaluable patients to be included in the primary analysis population) would provide the trial with at least 90% power for the assessment of the primary end point within a noninferiority margin of 10%****[, but]* ***[t]he data review committee recommended enrollment up***

***to the protocol-allowed maximum of 1450 patients [and Spero], in consultation with the FDA, revised the noninferiority margin to 12.5%.***" While it reiterated certain data points as set forth in the 2020 IDWeek Presentation slides (*e.g.*, the by-pathogen clinical and microbiological response at test-of-cure in the micro-ITT population for the gram-negative pathogens (Enterobacterales) remained at 65.9% in ertapenem), it adjusted certain others, *e.g.*, it ***reduced*** the by-pathogen clinical and microbiological response at test-of-cure in the micro-ITT population for the gram-negative pathogens (Enterobacterales) to ***59.7% in tebipenem HBr*** (***down from the 63.0% stated*** in the 2020 IDWeek Presentation Slides) as shown in Figure 9 below. Its conclusion, based on the data from the micro-ITT population, which did not change from what Spero first stated in the 2020 IDWeek Presentation Slides was that "***Oral tebipenem pivoxil hydrobromide was noninferior to intravenous ertapenem with respect to the primary end point of overall response at the test-of-cure visit (58.8% and 61.6% of the patients, respectively; weighted difference, −3.3 percentage points; 95% confidence interval [CI], −9.7 to 3.2)"*** as shown in Figure 10 below. It further stated, "***Results were consistent across trial populations and subpopulations, infection types, and causative uropathogens***."

*Figure 8:*

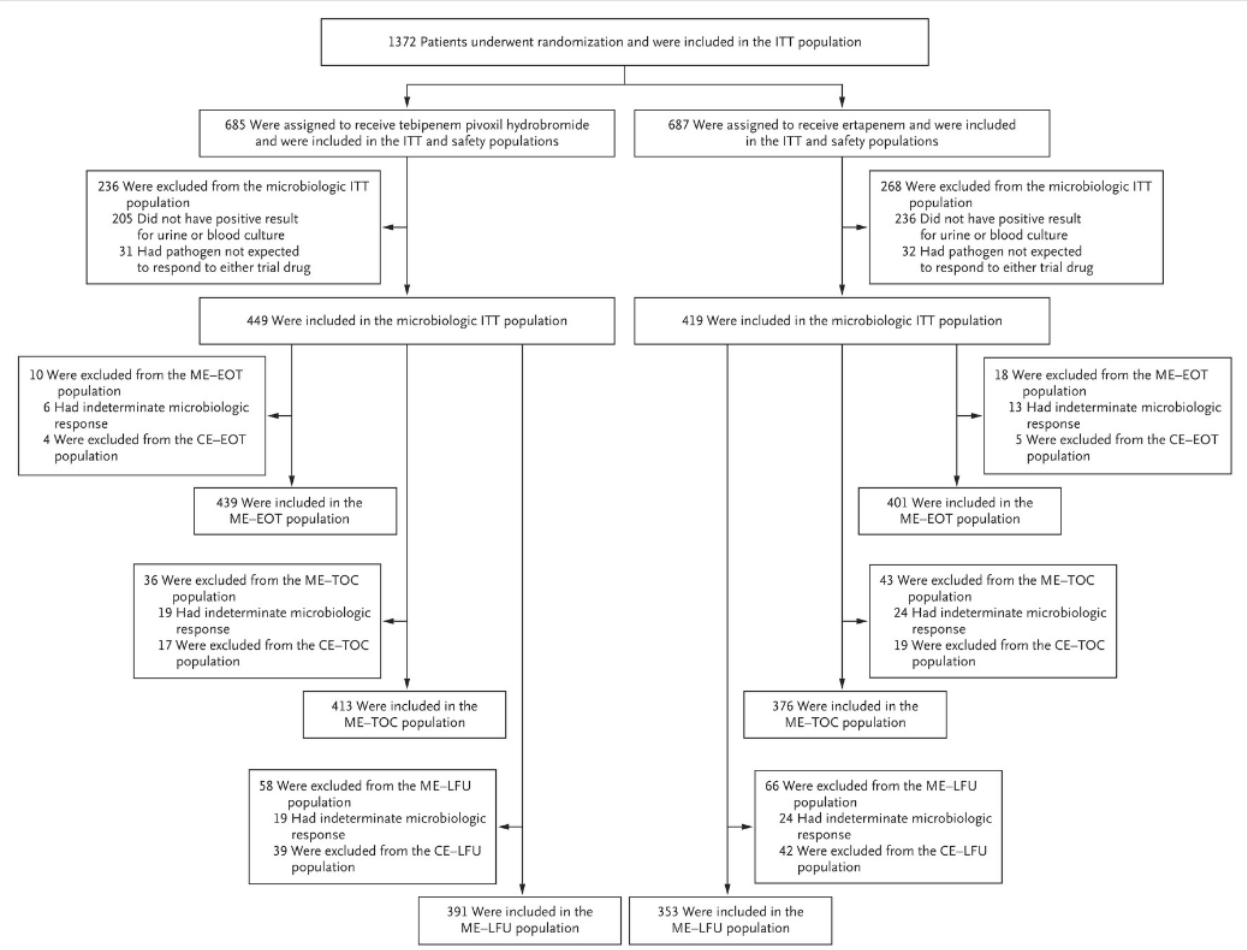



*Figure 9:*

Table S7. By-pathogen clinical and microbiological response at test-of-cure (microbiological intent-to-treat population)

| | Clinical Responses | | Microbiological Responses | |
|---|---|---|---|---|
| **Baseline Pathogen*** | **TBP-PI-HBr n/N (%)** | **Ertapenem n/N (%)** | **TBP-PI-HBr n/N1 (%)** | **Ertapenem n/N1 (%)** |
| Overall | 418/449 (93.1) | 392/419 (91.6) | 306/493 (62.1) | 296/455 (65.1) |
| Enterobacterales | 368/397 (92.7) | 363/386 (94.0) | 249/417 (59.7) | 265/402 (65.9) |
| *Escherichia coli* | 270/287 (94.1) | 260/270 (96.3) | 180/287 (62.7) | 176/270 (65.2) |
| *Klebsiella pneumoniae* | 46/53 (86.8) | 64/71 (90.1) | 24/53 (45.3) | 45/71 (63.4) |
| *Proteus mirabilis* | 32/35 (91.4) | 21/23 (91.3) | 17/35 (48.6) | 16/23 (69.6) |
| *Enterobacter cloacae* | 10/11 (90.9) | 7/8 (87.5) | 6/11 (54.5) | 4/8 (50.0) |
| Gram-positive | 71/76 (93.4) | 44/51 (86.3) | 57/76 (75.0) | 31/53 (58.5) |
| *Enterococcus faecalis* | 53/58 (91.4) | 33/36 (91.7) | 39/58 (67.2) | 20/36 (55.6) |
| *Enterococcus faecium* | 5/5 (100) | 2/2 (100) | 5/5 (100) | 2/2 (100) |
| *Staphylococcus aureus* | 5/5 (100) | 7/8 (87.5) | 5/5 (100) | 3/8 (37.5) |
| *Staphylococcus saprophyticus* | 4/4 (100) | 3/6 (50.0) | 4/4 (100) | 5/6 (83.3) |
| Enterobacterales resistance phenotype† | | | | |
| ESBL-positive | 92/105 (87.6) | 81/85 (95.3) | 58/106 (54.7) | 53/86 (61.6) |
| Fluoroquinolone-non-susceptible | 143/159 (89.9) | 137/146 (93.8) | 89/165 (53.9) | 91/149 (61.1) |
| Trimethoprim-sulfamethoxazole-resistant | 155/168 (92.3) | 160/168 (95.2) | 99/172 (57.6) | 109/170 (64.1) |

ESBL, extended spectrum β-lactamase; FQ, fluoroquinolone; MIC = minimum inhibitory concentration; TBP-PI-HBr, tebipenem pivoxil hydrobromide; TMP-SMX, trimethoprim-sulfamethoxazole; TOC, Test-of-Cure. N= number of patients with a given pathogen; N1=total number of isolates; A patient could have more than 1 pathogen. Multiple isolates of the same species/category from the same patient were counted only once based on the isolate with the highest MIC to study drug.

* Only pathogens with at least 5 isolates in either treatment group are included.

† Resistance phenotypes defined as ESBL-positive = ceftazidime MIC ≥2 μg /mL (or ceftriaxone MIC ≥2 μg /mL if ceftazidime susceptibility was not available); FQ-non-susceptible = levofloxacin MIC ≥1 μg /mL; TMP/SMX-resistant = TMP/SMX MIC ≥4/76 μg /mL; pathogens may be included in more than one resistance category.

*Figure 10:*

**Table 2. Primary and Secondary Efficacy End Points (Microbiologic Intention-to-Treat Population).**

| End Point | Tebipenem Pivoxil Hydrobromide (N=449) | Ertapenem (N=419) | Treatment Difference (95% CI)* |
|---|---|---|---|
| | *number (percent)* | | *percentage points* |
| **Primary end point** | | | |
| Overall response at test-of-cure visit† | 264 (58.8) | 258 (61.6) | −3.3 (−9.7 to 3.2) |
| **Secondary end points** | | | |
| Overall response at end-of-treatment visit† | 437 (97.3) | 396 (94.5) | 2.8 (0.1 to 5.7) |
| Clinical response‡ | | | |
| Clinical improvement at day 5 | 336 (74.8) | 321 (76.6) | −1.9 (−7.6 to 3.8) |
| Clinical cure at end-of-treatment visit | 446 (99.3) | 410 (97.9) | 1.4 (−0.1 to 3.4) |
| Clinical cure at test-of-cure visit | 418 (93.1) | 392 (93.6) | −0.6 (−4.0 to 2.8) |
| Sustained clinical cure at late follow-up | 398 (88.6) | 377 (90.0) | −1.5 (−5.7 to 2.6) |
| Microbiologic response§ | | | |
| Response at day 5 | 427 (95.1) | 397 (94.7) | 0.3 (−2.7 to 3.4) |
| Response at end-of-treatment visit | 439 (97.8) | 403 (96.2) | 1.5 (−0.8 to 4.1) |
| Response at test-of-cure visit | 267 (59.5) | 266 (63.5) | −4.5 (−10.8 to 1.9) |
| Sustained response at late follow-up | 257 (57.2) | 244 (58.2) | −1.5 (−7.9 to 5.0) |

* Confidence intervals were calculated with the use of the method of Miettinen and Nurminen and the Cochran–Mantel–Haenszel test, with differences between the two trial groups summarized as weighted differences (stratified according to age at informed consent and diagnosis at baseline). Confidence intervals for secondary end points were not adjusted for multiplicity and were used to demonstrate consistency of the treatment effect with the primary end point; they cannot be used to infer effects.

† Overall response was defined as a composite of clinical cure and microbiologic response (see below) at the test-of-cure visit (on day 19, within a ±2-day window).

‡ Clinical improvement at day 5 was defined as improvement by at least one grade in at least one baseline sign or symptom of complicated urinary tract infection or acute pyelonephritis and no worsening of any baseline signs or symptoms and no new signs or symptoms of either infection that resulted in the initiation of a nontrial antibacterial therapy. Clinical cure was defined as a complete resolution or reduction of signs and symptoms of complicated urinary tract infection or acute pyelonephritis that were present at baseline and no new symptoms such that no further antimicrobial therapy was warranted. Late follow-up occurred at 25 days, within a ±2-day window.

§ Microbiologic response was defined as a reduction in the baseline uropathogen to less than $10^3$ colony-forming units per milliliter and a negative repeated blood culture if the blood culture was positive for a uropathogen at baseline.

128. The misrepresentations and omissions in the 4/6/2022 Press Release, the 4/7/2022 Form 8-K, and the 4/7/2022 NEJM Publication, as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective

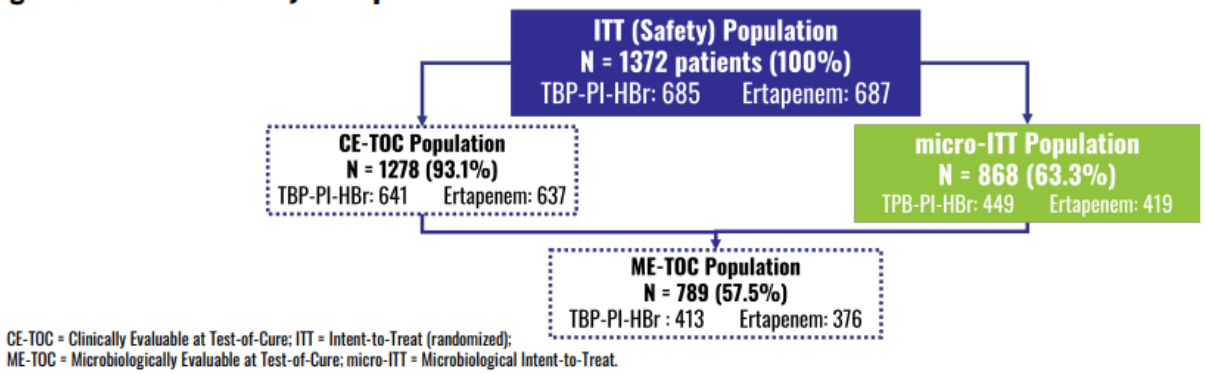
Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

129. On or about April 7, 2022, Spero presented at the Society of Hospital Medicine (SHM) Converge Conference held on April 7-10, 2022 (the "2022 SHM Conference"). Spero's website provided a link to materials presented at the conference. On information and belief, given that the presentation covered the ADAPT-PO Trial results and tebipenem HBr NDA, the 2022 SHM Conference statements were authorized and approved by the Individual Defendants.

(a) At the 2022 SHM Conference, Spero presented a poster titled "Oral Tebipenem Pivoxil is Non-Inferior to IV Ertapenem in Complicated Urinary Tract Infection (cUTI) and Acute Pyelonephritis (AP): ADAPT-PO Study" (the "2022 SHM Conference ADAPT-PO Trial Poster"). It displayed the micro-ITT population in Figure 11 below and displayed the percentages of patients in micro-ITT broken down by gram-negative and gram-positive pathogens in Figure 12 below. Its conclusion based on the data from the micro-ITT population was that, "***the primary objective was met: tebipenem pivoxil hydrobromide (600mg PO q8h) was non-inferior to ertapenem (1g IV q24h)"*** and ***"Overall response rates at TOC were similar between treatment groups (approximately 59% in the TBP-PI-HBr group vs. 62% in the ertapenem group) and were high and similar between treatment groups at EOT (>94% in both groups***)" as shown in Figure 13 below. The 2022 SHM Conference ADAPT-PO Trial Poster also confirmed that the NDA review for possible approval was on track stating, "***In January 2021, the FDA granted Priority Review designation and confirmed the acceptance for substantive review of the New Drug Application (NDA) and [t]he FDA has a set a PDUFA target action date of June 27, 2022***."

*Figure 11:*

**Figure 3. ADAPT-PO Analysis Populations**




CE-TOC = Clinically Evaluable at Test-of-Cure; ITT = Intent-to-Treat (randomized);
ME-TOC = Microbiologically Evaluable at Test-of-Cure; micro-ITT = Microbiological Intent-to-Treat.

*Figure 12:*

**Table 2. Uropathogens isolated from urine and/or blood at baseline (micro-ITT)**

| Baseline Pathogen† | TBP-PI-HBR (N=449) | Ertapenem (N=419) | Total (N=868) |
|---|---|---|---|
| **Enterobacterales** | **397 (88.4%)** | **386 (92.1%)** | **783 (90.2%)** |
| *Escherichia coli* | 287 (63.9%) | 270 (64.4%) | 557 (64.2%) |
| *Klebsiella pneumoniae* | 53 (11.8%) | 71 (16.9%) | 124 (14.3%) |
| *Proteus mirabilis* | 35 (7.8%) | 23 (5.5%) | 58 (6.7%) |
| *Enterobacter cloacae* | 11 (2.4%) | 8 (1.9%) | 19 (2.2%) |
| *Citrobacter freundii* | 4 (0.9%) | 3 (0.7%) | 7 (0.8%) |
| *Citrobacter koseri* | 3 (0.7%) | 4 (1.0%) | 7 (0.8%) |
| *Klebsiella oxytoca* | 4 (0.9%) | 3 (0.7%) | 7 (0.8%) |
| *Providencia rettgeri* | 4 (0.9%) | 3 (0.7%) | 7 (0.8%) |
| *Klebsiella variicola* | 2 (0.4%) | 4 (1.0%) | 6 (0.7%) |
| *Serratia marcescens* | 4 (0.9%) | 2 (0.5%) | 6 (0.7%) |
| *Morganella morganii* | 4 (0.9%) | 1 (0.2%) | 5 (0.6%) |
| **Gram-positive cocci** | **76 (16.9%)** | **51 (12.2%)** | **127 (14.6%)** |
| *Enterococcus faecalis* | 58 (12.9%) | 36 (8.6%) | 94 (10.8%) |
| *Staphylococcus aureus* | 5 (1.1%) | 8 (1.9%) | 13 (1.5%) |
| *S. saprophyticus* | 4 (0.9%) | 6 (1.4%) | 10 (1.2%) |
| *Enterococcus faecium* | 5 (1.1%) | 2 (0.5%) | 7 (0.8%) |

**Table 3. Per-patient baseline Enterobacterales pathogen resistance phenotypes**

| Enterobacterales Resistance phenotype ‡ | TBP-PI-HBR | Ertapenem |
|---|---|---|
| ESBL+ | 26.5% | 22.0% |
| FQ-non-susceptible | 40.2% | 37.8% |
| TMP-SMX-resistant | 42.4% | 43.5% |

‡ Per CLSI screening criteria: ESBL+ = ceftazidime MIC ≥2 µg/mL; fluoroquinolone (FQ)-non-susceptible = levofloxacin MIC ≥ 1 µg/mL; trimethoprim-sulfamethoxazole (TMP/SMX)-resistant = TMP-SMX MIC ≥ 4/76 µg/mL.

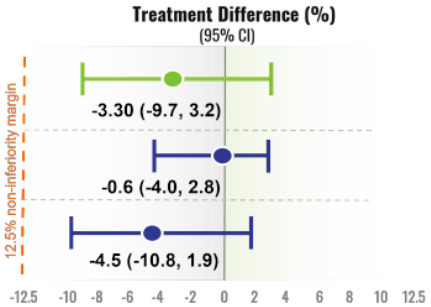
- The TBP-PI-HBr and ertapenem groups were well-matched in age and sex. Approximately 44% of patients were age ≥ 65. **(Table 1)**
- 90% of patients in the micro-ITT were infected with Enterobacterales. **(Table 2)**
- Infections caused by resistant Enterobacterales strains were common. **(Table 3)**

*Figure 13:*

**Figure 5. Primary and secondary efficacy endpoints at Test-of-Cure visit (micro-ITT population).**

| | TBP-PI-HBr | Ertapenem |
|---|---|---|
| **Overall response at TOC (%; n/N)** | **58.8%** 264/449 | **61.6%** 258/419 |
| **Clinical cure at TOC (%; n/N)** | **93.1%** 418/449 | **93.6%** 392/419 |
| **Microbiological eradication at TOC (%; n/N)** | **59.5%** 267/449 | **63.5%** 266/449 |

micro-ITT = microbiological Intent-to Treat; TOC = Test-of-Cure



(b) Also at the 2022 SHM Conference, Spero presented a poster titled "Clinical Stability Indicators Between Ertapenem and Tebipenem Pivoxil, and Oral Carbapenem, in Hospitalized Adults With Complicated Urinary Tract Infection" (the "2022 SHM Conference Clinical Poster"). It made materially false and misleading statements regarding the ADAPT-PTO Trial, stating that it "***demonstrated the non-inferiority of oral tebipenem HBr versus IV ertapenem in patients with cUTI/AP***."

130. The misrepresentations and omissions in the 2022 SHM Conference ADAPT-PO Trial Poster and 2022 SHM Conference Clinical Poster, as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

131. On April 11, 2022, Spero published an article in *Clinical and Translational Science* titled, "Bioequivalence of Two Oral Formulations of Tebipenem Pivoxil Hydrobromide in Healthy Subjects" (the 4/11/2022 Bioequivalence Article") that was posted to Spero's website, which reported the results of a trial analyzing whether the clinical formulation of tebipenem HBr used in the ADAPT-PO Trial and reported to be statistically non-inferior to IV ertapenem in the treatment of patients with cUTI/AP was bioequivalent to the oral tablet registration formulation of tebipenem HBr that will be marketed. It stated, "***[tebipenem HBr] prodrug was developed as the first oral***

***carbapenem for treatment of serious bacterial infections due to gram-positive and gram-negative bacteria, including drug-resistant pathogens***." It also stated that "***results of this study demonstrated that the clinical and registration formulations of [tebipenem HBr] were [bioequivalent].***"

132. The misrepresentations and omissions in the 4/11/2022 Bioequivalence Article, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

133. On April 14, 2022, Spero published an article in *American Society for Microbiology* titled, "Pharmacokinetics of Oral Tebipenem Pivoxil Hydrobromide in Subjects with Varying Degrees of Renal Impairment" (the "4/14/2022 Pharmacokinetics Article") that was posted to Spero's website, which provided results of a study evaluating the effects of TBP-PI-HBr in subjects with varying degrees of renal function. It stated, "***[tebipenem HBr] is an oral carbapenem prodrug antimicrobial agent with broad-spectrum activity that includes multidrug-resistant [MDR] Enterobacterales***" (gram-negative pathogens). It also stated, "***[tebipenem HBr] has the potential to address an important unmet need for a new oral therapy effective in the treatment of serious bacterial infections due to MDR Gram-negative pathogens***."

134. The misrepresentations and omissions in the 4/14/2022 Pharmacokinetics Article, as alleged in the preceding paragraph, were materially false and misleading because, as more fully

described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

135. On April 21, 2022, Spero issued a press release (the "4/21/2022 Press Release) announcing presentations at the 32nd European Congress of Clinical Microbiology and Infectious Diseases ("ECCMID") meeting held April 23-25, 2022, which provided a link to several presentation slides and posters on Spero's website.

(a) The 4/21/2022 Press Release provided a link to presentation poster #0213 titled "Efficacy of Tebipenem Pivoxil Hydrobromide in Patients with Complicated Urinary Tract Infection and/or Acute Pyelonephritis and Associated Bacteremia in ADAPT-PO" ("4/21/2022 ECCMID Poster 0213)." The 4/21/2022 ECCMID Poster #0213 provided secondary analysis of the ADAPT-PO Trial, particularly relating to the micro-ITT population separated into Enterobacterales and gram-positive categories, stating:

> · ***Oral TBP-PI-HBr was non-inferior to IV ertapenem in patients with cUTI/AP in the ADAPT-PO trial.***
> · ***The results from this secondary analysis found that clinical and microbiological outcomes for patients with bacteremia were comparable for those treated with oral TBP-PI-HBr and those treated with IV ertapenem***.
> · ***These results support the use of TBP-PI-HBr across a spectrum of patients with cUTI/AP*** including those with more a [sic] severe disease based on the presence of baseline bacteremia.

(b) The 4/21/2022 Press Release provided a link to Abstract #01140 presented on April 24, 2022 titled, "Plasma Pharmacokinetics and Intrapulmonary Penetration of Tebipenem in Healthy Subjects" (the "4/24/2022 ECCMID Abstract 01140"). 4/24/2022 ECCMID Abstract

01140 referenced the updated ADAPT-PO Trial results published in the 4/7/2022 NEJM Publication, stating that the ADAPT-PO Trial "***has demonstrated that oral tebipenem pivoxil hydrobromide was non-inferior to intravenous ertapenem for treating patients with complicated urinary tract infections, including acute pyelonephritis***."

(c) The 4/21/2022 Press Release also provided a link to presentation poster #0220, titled "Tebipenem Pivoxil Hydrobromide: Safety and Tolerability Profile of the First Oral Carbapenem for Complicated Urinary Tract Infection and Acute Pyelonephritis," which was presented on April 24, 2022 (the "4/24/2022 ECCMID Poster 0220"). It provided safety and tolerability results from the "Pivotal" ADAPT-PO Trial, stating "***[i]f approved, TBP-PI-HBr may provide an oral treatment option for patients with serious bacterial infections, including cUTI/AP with a safety /tolerability consistent with the carbapenem class***."

136. The misrepresentations and omissions in the 4/21/2022 Press Release, 4/21/2022 ECCMID Poster 0213, 4/24/2022 ECCMID Abstract 01140, and 4/24/2022 ECCMID Poster 0220, as alleged in the preceding paragraphs, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

137. On May 2, 2022, Spero published an article in *Antimicrobial Agents Chemotherapy* titled "Evaluation of Tebipenem Hydrolysis by ß-Lactamases Prevalent in Complicated Urinary Tract Infections" (the "5/2/2022 Hydrolysis Article") that was posted to Spero's website and that

provided results for tebipenem's stability to hydrolysis in organisms that cause cUTI. It stated that the "***the β-lactamase stability data of tebipenem together with in vitro antimicrobial activity of tebipenem and pharmacokinetics/pharmacodynamics (PK-PD) of TBI-PI-HBR support the development of TBP-PI-HBR as an oral drug to trat adult cUTI/AP.***"

138. The misrepresentations and omissions in the 5/2/2022 Hydrolysis Article, as alleged in the preceding paragraph, were materially false and misleading because, as more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

**2. *Reported Results Fraud***

139. Defendants made a series of filings and public statements reporting financial and operational metrics like revenues, net loss, direct research and development expenses and government contract payments, and available cash, without disclosing that they were being generated through, artificially inflated by, and subject to improper practices, unreported operational setbacks, and undisclosed risks and negative trends. These misstatements violated, *inter alia*, Regulation S-K, Item 303, 17 C.F.R. §229.303(a)(3)(i)-(ii) and (b)(2). The "Reported Results Fraud" included the following misstatements and omissions.

140. Spero announced its Q3 2020 financial results in a series of releases and filings made on November 5, 2020, including the following:

(a) On November 5, 2020, Spero issued and filed the 11/5/2020 Earnings Release. In it, Spero reported Q3 2020 quarterly net loss of $18.9 million, ($0.86 per common

share) on total revenue of $4 million, as compared to a Q3 2019 net loss of $17.7 million ($0.95 per common share) on revenues of $4.6 million. Contributing to these results was lower reimbursement in 2020 for qualified tebipenem HBr expenses under Spero's contract with BARDA. Also underlying these results was the progress Spero purportedly made in its ADAPT-PO Trial for tebipenem HBr. Defendant Mahadevia was quoted as saying, "***We made significant clinical progress in the third quarter with the announcement that the ADAPT-PO Trial met its primary endpoint***." He continued by expressing that Spero is "excited by the ***positive results seen in the ADAPT-PO trial***" and that the results "highlight the potential benefit oral tebipenem HBr could offer to patients with cUTI." Additionally, the earnings release reported that, as of September 30, 2020, Spero had $127.2 million in cash and cash equivalents on hand.

(b) On November 5, 2020, Spero filed the Q3 2020 10-Q. The Q3 2020 10-Q reported the same financial and operating results as were reported in the 11/5/2020 Earnings Release. It reported Q3 2020 quarterly net loss of $18.9 million, or $0.86 per common share, on total revenue of $4 million, which included the reimbursement of $3.76 million of qualifying expenses incurred in connection with the tebipenem HBr BARDA contract. Direct research and development of tebipenem HBr accounted for $10.6 million of Spero's Q3 2020 expenses. It also reported that, as of September 30, 2020, Spero had $127.2 million in cash, cash equivalents and marketable securities. In addition, its Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") section stated that Spero's "***ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates***." It proceeded to tout tebipenem HBr as its "***most advanced product candidate*** … designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections," to

describe "***positive topline results for the Phase 3 ADAPT-PO clinic trial***," and, based on the positive topline results, to express its intention to ***submit an NDA for tebipenem HBr to the FDA in the second quarter of 2021***.

(c) Accompanying the Q3 2020 10-Q were SOX certifications filed by the Defendant Mahadevia with the SEC. Defendant Mahadevia executed a Section 906 Certification, dated November 5, 2020, attesting that "[t]he Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and [t]he information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company." He also executed a Section 302 Certifications dated November 5, 2020, as quoted and discussed in the Internal Controls Fraud section herein.

141. Spero announced its Q4 2020 quarterly and full year 2020 results on March 11, 2021, including the following:

(a) On March 11, 2021, Spero issued and filed the 3/11/2021 Earnings Release. In it, Spero reported Q4 2020 net loss for the fourth quarter and year ended December 31, 2020 of $18.6 million ($0.68 per common share) and $78.8 million ($3.52 per common share), respectively on total revenue of $1.9 million in Q4 2020 and $9.3 million for full year 2020, as compared to a Q4 2019 net loss of $25 million ($1.31 per common share) and 2019 full year net loss of $60.9 million ($3.35 per common share). Contributing to these results was lower reimbursement in 2020 for qualified tebipenem HBr expenses under Spero's contract with BARDA, as well as lower collaboration revenue. Also underlying these results was the purported progress Spero made in the development of tebipenem HBr. Defendant Mahadevia was quoted as saying that chief among Spero's yearly milestones "was our announcement in September 2020 that ***the tebipenem HBr ADAPT-PO Phase 3 clinical trial*** in complicated urinary tract infection … ***met its primary***

***endpoint***." He also stated that "we look forward to another productive year in 2021, as ***we advance tebipenem HBr towards an NDA submission in the second half of 2021*** and move closer to potentially addressing the unmet needs of the estimated 2.7 million cUTI and AP patients in the United States." Additionally, the earnings release reported that, as of December 31, 2020, Spero had $126.9 million in cash, cash equivalents and marketable securities on hand.

(b) On March 11, 2021, Spero filed the 2020 10-K. The 2020 10-K reported substantially the same financial and operation results as the 3/11/2021 Earnings Release. It reported net loss for the year ended December 31, 2020 of $78.3 million ($3.52 per common share) on total revenue of $9.3 million, as compared to net loss of $60.9 million ($3.35 per common share) on total revenue of $18.1 million for the year ended December 31, 2019. The 2020 year-end revenue included the reimbursement of $7.9 million of qualifying expenses incurred in connection with the tebipenem HBr BARDA contract. Direct research and development of tebipenem HBr accounted for $41.9 million of Spero's 2020 yearly expenses. It also reported that, as of December 31, 2020, Spero had $126.9 million in cash, cash equivalents and marketable securities. In addition, its MD&A section stated, Spero's "***ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates***." It proceeded to tout tebipenem HBr as its "most advanced product candidate … designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections."

(c) Accompanying the 2020 10-K were SOX certifications filed by the Individual Defendants with the SEC. Defendants Mahadevia and Shukla executed a Section 906 Certification, dated March 11, 2021, attesting that "[t]he Annual Report for the year ended December 31, 2020 (the 'Form 10-K') of the Company fully complies with the requirements of

section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company." They also executed Section 302 Certifications dated March 11, 2021, as quoted and discussed in the Internal Controls Fraud section herein

142. Spero announced its Q1 2021 financial results in a series of releases and filings made on May 6, 2021, including the following:

(a) On May 6, 2021, Spero issued and filed the 5/6/2021 Earnings Release. In it, Spero reported Q1 2021 quarterly net loss of $19.4 million, ($0.66 per common share) on total revenue of $7.3 million, as compared to a Q1 2020 net loss of $23.3 million ($1.22 per common share) on revenues of $1.7 million. The revenue increase was primarily attributable to grant revenue received through the tebipenem HBr BARDA contract. Also underlying these results was the purported progress of the development of tebipenem HBr which included purportedly positive feedback from the FDA at a pre-NDA meeting. Defendant Mahadevia was quoted as saying, "We recently completed a pre-NDA meeting for tebipenem HBr with the FDA and ***received feedback indicating that the format and content of the planned data package we intend to include in our NDA will be sufficient to support the submission.*** This regulatory milestone keeps us on track to submit the NDA in the second half of the year as we work to transition to a commercial-stage organization" Additionally, the earnings release reported that, as of March 31, 2021, Spero had $115.7 million in cash, cash equivalents and marketable securities on hand.

(b) On May 6, 2021, Spero filed the Q1 2021 10-Q. The Q1 2021 10-Q reported the same financial and operating results as were reported in the 5/6/2021 Earnings Release. It reported Q1 2021 quarterly net loss of $19.4 million, or $0.66 per common share, on total revenue of $7.3 million, which included the reimbursement of $6.3 million of qualifying expenses incurred

in connection with the tebipenem HBr BARDA contract. Direct research and development of Tebipenem HBr accounted for $10.1 million of Spero's Q1 2021 expenses. It also reported that, as of March 31, 2021, Spero had $115.7 million in cash, cash equivalents and marketable securities. In addition, its MD&A section stated Spero's "ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates." It proceeded to tout tebipenem HBr as its "***most advanced product candidate*** … designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections," explain that Spero had c***ompleted a pre-NDA meeting with the FDA for tebipenem HBr "to discuss the format and content of the submission***," represent that it "***achieved consensus that the package as described would allow review of the NDA***," and express its intention to submit an NDA for tebipenem HBr to the FDA in the second half of 2021.

(c) Accompanying the Q1 2021 10-Q were SOX certifications filed by the Individual Defendants with the SEC. Defendants Mahadevia and Shukla executed a Section 906 Certification, dated May 6, 2021, attesting that "[t]he Quarterly Report for the quarter ended March 31, 2021 (the 'Form 10-Q') of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company." They also executed Section 302 Certifications dated May 6, 2021, as quoted and discussed in the Internal Controls Fraud section herein.

143. Spero announced its Q2 2021 financial results in a series of releases and filings made on August 5, 2021, including the following:

(a) On August 5, 2021, Spero issued and filed the 8/5/2021 Earnings Release. In it, Spero reported Q2 2021 quarterly net loss of $18.6 million, ($0.63 per common share) on total revenue of $5.1 million, as compared to a Q2 2020 net loss of $17.5 million ($0.85 per common share) on revenues of $1.7 million. Contributing to these results was an increase in grant revenue received through the tebipenem HBr BARDA contract. Also underlying these results was the continuing development and advancement of tebipenem HBr. Defendant Mahadevia was quoted as saying, "During the second quarter, we achieved key milestones which has us well positioned for future success, as ***we work to submit the tebipenem HBr NDA***, transition to a commercial organization, and advance our clinical-stage pipeline." Defendant Mahadevia also emphasized that Spero's primary focus looking forward is to "***advance tebipenem HBr towards an NDA filing this year, which moves [Spero] closer to providing an oral treatment for potentially millions of patients with complicated urinary tract infection***." Additionally, the earnings release reported that, as of June 30, 2021, Spero had $99.2 million in cash, cash equivalents and marketable securities on hand.

(b) On August 5, 2021, Spero filed the Q2 2021 10-Q. The Q2 2021 10-Q reported the same financial and operating results as were reported in the 8/5/2021 Earnings Release. It reported Q2 2021 quarterly net loss of $18.6 million, or $0.63 per common share, on total revenue of $5.1 million, which included the reimbursement of $1.9 million of qualifying expenses incurred in connection with the tebipenem HBr BARDA contract. Direct research and development of tebipenem HBr accounted for $6.4 million of Spero's Q2 2021 expenses. It also reported that, as of March 31, 2021, Spero had $99. 2 million in cash, cash equivalents and marketable securities. In addition, its MD&A section stated Spero's "ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and

eventual commercialization of one or more of our product candidates." It proceeded to tout tebipenem HBr as its "***most advanced product candidate*** … designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections," explain that it was "***currently performing integrated analyses in conjunction with the NDA*** and ***drafting sections of the NDA both at the study and summary level***," and express its intention to submit an NDA for tebipenem HBr to the FDA in the fourth quarter of 2021.

(c) Accompanying the Q2 2021 10-Q were SOX certifications filed by the Individual Defendants with the SEC. Defendants Mahadevia and Shukla executed a Section 906 Certification, dated August 5, 2021, attesting that "[t]he Quarterly Report for the quarter ended June 30, 2021 (the 'Form 10-Q') of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company." They also executed Section 302 Certifications dated June 30, 2021, as quoted and discussed in the Internal Controls Fraud section herein.

144. Spero announced its Q3 2021 financial results in a series of releases and filings made on November 10, 2021, including the following:

(a) On November 10, 2021, Spero issued and filed the 11/10/2021 Earnings Release. In it, Spero reported Q3 2021 quarterly net loss of $22.5 million, ($0.70 per common share) on total revenue of $3.1 million, as compared to a Q3 2020 net loss of $18.9 million ($0.86 per common share) on revenues of $4 million. Contributing to these results was a decrease in qualified expenses incurred under the tebipenem HBr BARDA contract. Also underlying these results was the continued development of tebipenem HBr and Spero's submission of an NDA. Defendant Mahadevia stated that "chief among [Spero's] accomplishments ***was our recent NDA***

***submission for tebipenem HBr***, which, if approved, would make it the first oral carbapenem antibiotic available for use in cUTI." He also said that Spero "entered into a revenue interest financing agreement with HealthCare Royalty Partners, providing [it] with non-dilutive capital to support tebipenem's anticipated launch." Additionally, the earnings release reported that, as of September 30, 2021, Spero had $123.4 million in cash, cash equivalents and marketable securities on hand.

(b) On November 10, 2021, Spero filed the Q3 2021 10-Q. The Q3 2021 10-Q reported the same financial and operating results as were reported in the 11/10/2021 Earnings Release. It reported Q3 2021 quarterly net loss of $22.5 million, or $0.70 per common share, on total revenue of $3.1 million, which included the reimbursement of $721,000 of qualifying expenses incurred in connection with the tebipenem HBr BARDA contract. Direct research and development of tebipenem HBr accounted for $5.7 million of Spero's Q3 2021 expenses. It also reported that, as of September 30, 2021, Spero had $123.4 million in cash, cash equivalents and marketable securities. In addition, its MD&A section stated Spero's "ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates." It proceeded to tout tebipenem HBr as its "***most advanced product candidate*** … designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections," report that it "***submitted an NDA to the FDA for tebipenem HBr tablets for the treatment of complicated urinary tract infections, including pyelonephritis***," and explain that "[b]ased on standard FDA review timelines, the FDA has a 60-day period to determine whether the NDA is complete and acceptable for review." It also reported that Spero entered into a "revenue interest financing agreement with certain entities managed by HealthCare Royalty Management, LLC" and

"intend[ed] to use the proceeds from the Revenue Interest Agreement and existing cash on hand ***to prepare for the anticipated launch of tebipenem HBr***."

(c) Accompanying the Q3 2021 10-Q were SOX certifications filed by the Individual Defendants with the SEC. Defendants Mahadevia and Shukla executed a Section 906 Certification, dated November 10, 2021, attesting that "[t]he Quarterly Report for the quarter ended September 30, 2021 (the 'Form 10-Q') of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company." They also executed Section 302 Certifications dated November 10, 2021, as quoted and discussed in the Internal Controls Fraud section herein.

145. Spero announced its Q4 2021 quarterly and full year 2021 results on March 31, 2022, including the following:

(a) On March 31, 2022, Spero issued and filed the 3/31/2022 Earnings Release. In it, Spero reported Q4 2021 net loss for the fourth quarter and year ended December 31, 2021 of $29.2 million ($0.90 per common share) and $89.8 million ($2.91 per common share) respectively on total revenue of $2.7 million in Q4 2020 and $18.3 million for full year 2020, as compared to a Q4 2020 net loss of $18.6 million ($0.68 per common share) and 2020 full year net loss of $78.8 million ($3.52 per common share). Contributing to these results was an increase in grant revenue received through the tebipenem HBr BARDA contract. Also underlying these results was purportedly continued optimism of obtaining FDA approval for tebipenem HBr despite recently identified deficiencies in Spero's NDA. Defendant Mahadevia was quoted as saying, "***we believe there would be sufficient time to progress to labeling discussions within the existing PDUFA timeframe***" and that "***[w]e continue to prepare for an anticipated launch of tebipenem HBr in***

***the second half of 2022, as we work with the FDA***." Additionally, as of December 31, 2021, Spero had $146.4 million in cash, cash equivalents and marketable securities on hand.

(b) On March 31, 2022, Spero filed the 2021 10-K. The 2021 10-K reported substantially the same financial and operation results as the 3/31/2022 Earnings Release. It reported net loss for the year ended December 31, 2021 of $89.8 million ($2.91 per common share) on total revenue of $18.3 million, as compared to net loss of $78.3 million ($3.52 per common share) on total revenue of $9.3 million for the year ended December 31, 2020. The 2021 year-end revenue included the reimbursement of $9.9 million of qualifying expenses incurred in connection with the tebipenem HBr BARDA contract. Direct research and development of Tebipenem HBr accounted for $28.9 million of Spero's 2021 yearly expenses. It also reported that, as of December 31, 2021, Spero had $146.4 million in cash, cash equivalents and marketable securities. In addition, its MD&A section stated that Spero's "ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates." It proceeded to tout tebipenem HBr as its "***most advanced product candidate*** … designed to be the first broad-spectrum oral carbapenem-class antibiotic for use to treat certain bacterial infections that cause complicated urinary tract infections," express that it "intend[s] to work with the FDA to seek to resolve the deficiencies expeditiously," represent that the deficiency "notification does ***not reflect a final decision***," state that it "believe[s] there would be ***sufficient time to progress to labeling discussions within the existing PDUFA timeframe***, given how early in the review period those discussions were originally scheduled to occur," and explain that Spero will "***continue to prepare for an anticipated commercial launch of tebipenem HBr in the second half of 2022***" as it works with the FDA.

(c) Accompanying the 2021 10-K were SOX certifications filed by the Individual Defendants with the SEC. Defendants Mahadevia and Shukla executed a Section 906 Certification, dated March 31, 2022, attesting that "[t]he Annual Report for the year ended December 31, 2021 (the 'Form 10-K') of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company." They also executed Section 302 Certifications dated March 31, 2022, as quoted and discussed in the Internal Controls Fraud section herein.

146. The foregoing statements in ¶¶139-145 were materially false and misleading because they reported financial metrics and results like revenues, net loss, direct research and development expenses and government contract payments, and available cash without disclosing that they were being generated through, artificially inflated by, and subject to improper practices, unreported operational setbacks, and undisclosed risks and negative trends, as alleged herein, including those detailed by the CW accounts set forth in the "Undisclosed, Material, Negative Facts" section *supra* and the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*. Those sections, along with the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, illustrate, *inter alia*, that the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval. Moreover, while Defendants admitted that they were in early and frequent contact with the FDA, in advance of and following the NDA submission, the CW statements indicate that Spero faced an atypically large number of FDA questions and concerns about the tebipenem HBr NDA submission, including regarding clinical issues, to which responses

were necessary multiple times a week. It was materially false and misleading to reference positive metrics, developments, and milestones of the ADAPT-PO Trial and tebipenem HBr's progress toward FDA approval, while omitting timely and fulsome disclosure of the undisclosed risks and negative trends arising from an insufficiently evaluable patient population and deficient data in the ADAPT-PO Trial, and FDA's frequent expressed concerns. It was also materially false and misleading to highlight progress toward FDA approval of tebipenem HBr, particularly during the time Defendants were engaged in active discussions with the FDA, without disclosing these undisclosed risks and negative trends. As such, these misstatements and omissions in ¶¶139-145 violated, *inter alia*, Regulation S-K, Item 3030, 17 C.F.R. §229.303(a)(3)(i)-(ii) and (b)(2)..

**3. *Internal Controls Fraud***

147. During the Class Period, Defendants also made a series of public statements and filings regarding Spero's internal controls that were materially false and misleading. Specifically, Defendants Mahadevia and Shukla signed and SOX certified quarterly and annual reports by Defendant Spero, and in doing so, made materially false and misleading statements and omissions.

148. Spero's 2020 10-K, filed with the SEC on March 11, 2021, was signed and SOX certified by Defendants Mahadevia and Shukla and stated that the financial information contained in the 2020 10-K was accurate and disclosed any material changes to Spero's internal control over financial reporting. Specifically, Defendants Mahadevia and Shukla certified:

I, [Ankit Mahadevia, Satyavrat Shukla], certify that:

1. I have reviewed this Annual Report on Form 10-K of Spero Therapeutics, Inc.;

2. Based ***on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;***

3. Based ***on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the***

***financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;***

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. ***The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):***

   a) ***all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and***

   b) ***any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting***.

149. On March 31, 2022, Spero filed the 2021 10-K, signed and SOX certified by Defendants Mahadevia and Shukla with the same language as used in the 2020 10-K certifications alleged above, stating the financial information contained in Spero's 2021 10-K was accurate and disclosed any material changes to Spero's internal control over financial reporting.

150. On November 5, 2020, Spero filed the Q3 2020 10-Q, with SOX certifications signed by Defendant Mahadevia certifying that the financial information contained in Spero's Q3 2020 10-Q was accurate and disclosed any material changes to Spero's internal control over financial reporting. Specifically, Defendant Mahadevia certified:

I, [Ankit Mahadevia], certify that:

1. I have reviewed this quarterly report on Form 10-Q of Spero Therapeutics, Inc.;

2. ***Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;***

3. ***Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;***

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. ***The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):***

a) ***All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and***

b) ***Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.***

151. On May 6, 2021, Spero filed the Q1 2021 10-Q, with SOX certifications signed by Defendants Mahadevia and Shukla certifying that the financial information contained in Spero's Q1 2020 10-Q was accurate and disclosed any material changes to Spero's internal control over financial reporting. Specifically, Defendants Mahadevia and Shukla certified:

I, [Ankit Mahadevia, Satyavrat Shukla], certify that:

1. I have reviewed this quarterly report on Form 10-Q of Spero Therapeutics, Inc.;

2. ***Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;***

3. ***Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;***

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. ***The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):***

a) ***All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and***

b) ***Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.***

152. Defendants Mahadevia and Shukla signed identical SOX certifications as those accompanying Spero's Q1 2021 10-Q alleged above, certifying that the financial information

contained in Spero's Q2 2021 10-Q, filed with the SEC on August 5, 2021, and Spero's Q3 2021 10-Q, filed with the SEC on November 10, 2021, were accurate and disclosed any material changes to Spero's internal control over financial reporting during those reporting periods.

153. The foregoing statements in ¶¶147-152 were materially false and misleading because, *inter alia*: (a) the SEC filings in which they were made did, in fact, contain untrue statements of a material fact and omitted to state material facts necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered and (b) the fraud alleged herein involved management and other employees with a significant role in Spero's internal controls over financial reporting, and yet, it was not disclosed to Spero's auditors or to the audit committee of Spero's Board of Directors. As more fully described in the "Undisclosed, Material, Negative Facts" section *supra*, the "Defendants' Knowledge Or Reckless Disregard Of Red Flags" section *infra*, and the CW statements set forth in those sections, and the "Partial Corrective Disclosures Incrementally Revealed the Frauds" section *infra*, the undisclosed fraud, and the associated material misstatements and omissions, arose from the fact that the ADAPT-PO Trial lacked a sufficiently evaluable patient population and failed to generate data demonstrating that tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

**4. *Partial Corrective Disclosures Incrementally Revealed The Frauds***

154. During the Class Period, before the truth of Defendants' fraud was partially revealed, the market as a whole remained in the dark as to the deficiencies in the evaluable patient population of the ADAPT-PO Trial and the insufficiency of the ADAPT-PO Trial data to support Spero's NDA for tebipenem HBr, including the FDA's concerns about the Spero's decision to factor in the microbiological intent-to-treat (micro-ITT) population patients with Gram-positive

bacteria, and the inability of the ADAPT-PO Trial data to satisfy FDA's pre-specified non-inferiority margin. The market, including analysts following Spero, expected that Spero was able to make, and did make, a sufficient, data-supported NDA submission to the FDA based on analysis of appropriate patients that could have supported approval of tebipenem HBr.

155. For example, in its January 4, 2022 analyst report, Cowen noted that Spero's NDA was given QIDP, Fast Track and Priority Review with a June 27, 2022 PDUFA date and that although management expected an Advisory Committee to provide the FDA with independent advice from outside experts about the NDA submission, Cowen believed FDA approval of tebipenem HBr was highly likely, as "Spero has expressed confidence in the robust NDA data package, including data expected to be published in the spring, extensive post-market data from tebipenem use (including pediatric use) in Japan, pre-clinical tox, and positive data from the Ph3 ADAPT-PO trial." Similarly, in its March 21, 2022 analyst report, H.C. Wainwright & Co. noted that "the NDA submission included previously communicated positive data from the Phase 3 ADAPT-PO trial," which "showed that ADAPT-PO met its primary endpoint by demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous (IV) ertapenem in the treatment of patients with cUTI and patients with acute pyelonephritis (AP)."

156. Thus, the market was shocked on March 31, 2022, when Spero issued an after-hours press release that was filed with the SEC after the close of the markets, as an attachment to a Form 8-K (the "3/31/2022 Form 8-K") signed by Joseph, announcing that "***[t]he U.S. Food and Drug Administration (FDA) has notified Spero that, as part of its ongoing review of Spero's New Drug Application (NDA) for tebipenem HBr, it has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time***."

157. On this news, Spero's stock price fell $1.59 per share, or 18.28%, on exceptionally high volume, from a close of $8.70 per share on March 31, 2022, to close at $7.11 per share on April 1, 2022.

158. As alleged herein, Defendants' ongoing misrepresentations and omissions extended the fraud, muting the effects of the March 31, 2022 partial corrective disclosure and maintaining artificial inflation in Spero's stock price. Indeed, due to Defendants' reassurances, some analysts remained cautiously optimistic. For example, in its March 31, 2022 analyst report, Cantor Fitzgerald reiterated its Overweight rating and $27 price target stating, "[a]lthough this announcement creates some near-term uncertainty, we remain confident in the approvability of tebipenem HBr and the market opportunity for the drug." In its April 1, 2022 analyst report, Berenberg Capital Markets reiterated its Buy rating and a $44 price target stating, "[a]lthough serious, the letter of deficiency from the FDA is NOT a final decision" and "deficiencies are undisclosed at this time." In its April 1, 2022 analyst report, Cowen expressed its belief that "SPRO has a high-level understanding of the deficiencies and that the issues may not be a complete surprise for SPRO" and also noted that "[m]gmt remains optimistic for approval and has not changed the ramp of commercial prep spend for 2022."

159. On May 3, 2022, Spero issued a press release that was filed with the SEC as an attachment to a Form 8-K (the "5/3/2022 Form 8-K") signed by Joseph, announcing "that it ***will immediately defer current commercialization activities for tebipenem HBr based on feedback from a recent Late Cycle Meeting (LCM) with the U.S. Food and Drug Administration (FDA) regarding Spero's New Drug Application (NDA) for tebipenem HBr***[,]" and that, "[a]lthough the review is still ongoing and the FDA has not yet made any final determination regarding

approvability, the ***discussion suggested that the data package may be insufficient to support approval during this review cycle***." The press release further stated,

> ***In evaluating the efficacy of tebipenem HBr in the Phase 3 (ADAPT-PO) cUTI study, the FDA conducted a separate analysis of the microbiological intent-to-treat (micro-ITT) population, relative to the prespecified analysis as set forth in the previously submitted and reviewed protocol and statistical analysis plan for ADAPT-PO. The effect of this new analysis was to reduce the number of evaluable patients in the primary analysis population compared with those resulting from the trial's pre-specified micro-ITT population as outlined in the statistical analysis plan. As a result, the FDA considers that the pre-specified non-inferiority (NI) margin of -12.5% was not met.***

Further, the press release stated that, "[i]n connection with this development, ***Spero announced that it is undertaking a reduction in its workforce by approximately 75% and a restructuring of its operations to reduce operating costs and reallocate resources***."

160. Analysts rapidly distilled this information to the market. For example, in its May 3, 2022 analyst report, Oppenheimer explained that the FDA's own analysis on the micro-ITT population in the ADAPT-PO Trial excluded patients infected with a pathogen called Enterococcus, a gram-positive pathogen which usually accounts for 10%-15% of cUTIs and accounted for about 15% of the patients in the ADAPT-PO Trial with cUTI. This led to a reduction of the number of evaluable patients from the pre-specified micro-ITT population of 868 patients (which included all of the gram-negative and gram-positive pathogens) to 734 patients (which excluded the Enterococcus gram-positive pathogens). As a result, the non-inferiority margin increased beyond pre-specified upper limit non-inferiority margin of -12.5%.

161. On this news, Spero's stock price sharply declined an additional $3.24 per share, or 63.65%, on massive volume, from a close of $5.09 per share on May 2, 2022, to close at $1.85 per share on May 3, 2022.

162. Analysts also reacted negatively to this news. For example, in their May 3, 2022 analyst reports, both Berenberg Capital Markets and Cowen called the news "disappointing." In

its May 3, 2022 analyst report, Oppenheimer downgraded its rating with no price target, stating, "FDA's exclusion of Enterococcus species was a surprise to us." In a May 3, 2022 analyst report, an Evercore analyst called the news "shocking" saying, "the series of events with SPRA have rattled my (and investors') confidence and with finite resources and early stage anti-infectives, it's no longer a name we can recommend owning." Underscoring the degree to which analysts had been dependent on truthful updates from the company, the Evercore analyst also stated that "it's hard to know exactly what the agency is thinking."

163. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Spero stock, Plaintiffs and other Class Members have suffered significant losses and damages.

**F. Additional Facts Probative of Scienter**

164. A strong inference of Defendants' scienter is evidenced through a holistic examination of the facts and circumstances.

***1. Defendants' Knowledge Or Reckless Disregard Of Red Flags***

165. For many of the same reasons why Defendants' alleged misstatements and omissions were materially false or misleading when made, there is also a strong inference that they were made with the requisite scienter.

166. As discussed herein above, including in the "Undisclosed, Material, Negative Facts" and the "Partial Corrective Disclosures Incrementally Revealed The Frauds" sections *supra*, the allegations herein evidence the Defendants' actual knowledge or – at worst – reckless disregard of facts causing their alleged misstatements and omissions, as pled in the "Materially False And Misleading "Statements & Omissions" section *supra*, to be materially false and misleading.

167. In a series of partial corrective disclosures, as pled herein, Spero admitted in March and May 2022 that the ADAPT-PO Trial contained "deficiencies that preclude discussion of

labeling and post-marketing requirements / commitments" with the FDA and that the trial's "data package may be insufficient to support approval" by the FDA. Specifically, in the FDA's analysis of the ADAPT-PO Trial data, the gram-positive patients were not part of the evaluable patient population, and their exclusion meant that the trial could not meet the required non-inferiority margin of -12.5% when tebipenem HBr was compared against IV ertapenem.

168. Defendants knowingly opted to proceed with the ADAPT-PO Trial with an enrollment of 1,372 patients, despite the trial's being eligible for a maximum enrollment of 1,450. As discussed in the 4/7/2022 NEJM Publication, Defendants made this decision despite the fact that ***a data review committee*** – after performing a "blinded reassessment of the sample size after response data were available from 70% of the patents at the test-of-cure visit to confirm the initial sample-size estimate as adequate or to recommend an increase in sample size to ensure adequate power for measurement of the primary endpoint" – "***recommended[ed] an increase in sample size to ensure adequate power for measurement of the primary endpoint***." Specifically, as reported in the 4/7/2022 NEJM Publication, "***The data review committee recommended enrollment up to the protocol-allowed maximum of 1,450 patients***," but Defendants ***chose to not increase the trial enrollment***.

169. Thus, Defendants effectively self-selected the slenderness of their own margin for error within the ADAPT-PO Trial's patient population. As CW5 stated, based on discussions around Spero's LCM meeting with the FDA, the agency chose to exclude patients infected with gram-positive bacteria because the trial's comparison drug, IV ertapenem, was not indicated (*i.e.*, FDA approved) to treat gram-positive bacteria in cUTI. That rationale is neither unsupportable nor unforeseeable. Defendants knowingly chose to proceed with the ADAPT-PO Trial, during the

early stages of the COVID19 pandemic, with less than the maximum number of permissibly enrolled patients, despite knowing that a sizable minority of them had gram-positive infections.

170. Moreover, Defendants had ample, ongoing opportunity to inquire about and confirm the sufficiency of the ADAPT-PO Trial's data package through ***admittedly direct communications with the FDA***. Back on March 29, 2019 – 18 months before the Class Period – Spero announced that the FDA had granted tebipenem HBr a Fast Track Designation, which facilitates development and expedites review of certain high-value drug candidates. Consequently, ***Defendants were afforded the ability to interact more frequently with the FDA*** regarding tebipenem HBr's development ***their NDA submission was subject to a rolling review by the FDA***. Thus, Defendants enjoyed atypical access to the FDA that permitted them to discuss the sufficiency of the ADAPT-PO Trial's evaluable patient population and its ability to meet the non-inferiority margin and to receive the FDA's feedback on these issues.

171. Indeed, CW1, Spero's Director of Clinical Data Management, confirmed the faster pace of the FDA's Fast Track approval program, during which the FDA ***remains in much greater and frequent contact with applicants*** so that they can keep the application moving quickly. As CW1 put it, the FDA "***hold[s] your hand through the whole (process)***."

172. Defendants' own public statements, as alleged herein, corroborate this assessment. In September 2020, at the beginning of the Class Period, Defendant Mahadevia publicly discussed the upcoming "***pre-NDA meetings***" (plural) with the FDA. By March 2021, Defendants publicly disclosed that ***at least one pre-NDA meeting had occurred*** and, they expressly stated, under analyst questioning, that they had ***discussed*** "***the format and content of the planned data package***" that would accompany the tebipenem HBr NDA and that they had "***received feedback***" from the FDA. In September 20221, Defendant Mahadevia publicly referenced not only the pre-

NDA meeting from March 2021, but also "***multiple***" ***antecedent*** discussions with the FDA that concerned whether the ADAPT-PO Trial could support the NDA submission for tebipenem HBr.

173. CW2, an Associate Director in Spero's Regulatory Affairs Department, recounted the frenetic pacing of interactions with the FDA, which reached a crescendo during December 2021 through February 2022. As CW2 described, "Starting in December 2021, we got a lot of comments back from the FDA – requests for additional information on various topics: ***clinical***, non-clinical, CMC [Chemistry, Manufacturing, and Control]. That continued through December. January and February – that was the peak. ***We got questions from [the FDA] just about every week, even a couple times a week***." CW2 added, "We just got ***so many questions***. But ***a lot of them were clinical***." Indeed, CW2 said that the volume of FDA's questions was ***significantly higher*** than CW2 had seen during an NDA process in 20 years working in drug development and regulatory affairs. CW2 found the volume of questions "weird" and said that the level of scrutiny and frequent questions made CW2 wonder if the NDA might be shaky.

174. Moreover, Defendants' highly suspicious actions from February through May 2022 buttress a strong inference of their scienter. Specifically:

(a) CW1 found it odd that Spero let CW1 quit in February 2022 without ***any effort*** to retain CW1 – Spero's Director of Clinical Data Management – during the late stages of the NDA process for Spero's flagship drug candidate. CW1 noted that these events occurred shortly before the FDA formally sent a deficiency letter. As CW1 put it, "That made me suspicious. Maybe they knew this was coming."

(b) CW3, CW4, and CW6 all described a lack of candor and affirmative obfuscation by the Individual Defendants when they held a company-wide conference call in March 2022 to announce that the FDA had identified deficiencies in the tebipenem HBr NDA.

CW4 said that company leadership refused to disclose any details as to the nature of the deficiencies, CW3 said company leadership "did not want to comment on what it was," and CW6 said that company leadership "kept it very close to the vest" and did not disclose the actual deficiencies. As CW4 put it, "They knew details of the deficiencies, but they were not going to share it. They didn't let you know if it was regarding the research, the manufacturing, nothing. There was no indication of what it could have been."

(c) CW2 said that in early April 2022, as work was underway to prepare for the LCM with the FDA, Spero VP of Regulatory Affairs Jennifer Liscouski gave an instruction from the "leadership team" CW2 to restrict access to all the FDA submission documents for tebipenem HBr within the company's computer system to a tight circle of personnel – Defendant Mahadevia, a C-suite executive, three people in regulatory affairs (including CW2), and two people in CMC (Chemistry, Manufacturing, and Control).

(d) CW3, CW4, and CW6 all expressed being surprised at being swept up in a massive wave of layoffs right after Spero's LCM with the FDA. CW6 and CW6's colleagues were "stunned' at how fast Spero shut down most operations and officially terminated so many employees immediately after the LCM. According to CW6, Spero's LCM with the FDA occurred on a Thursday and by the next Tuesday (5 days later), the mass layoff was announced and employees learned that severance pay had already been transmitted into their bank accounts. As CW6 observed, such an abrupt, large-scale layoff required advanced coordination and planning among payroll, accounting, and leadership to get everything ready – leading CW6 to believe that the layoffs had been pre-planned. As CW6 put it, "Those plans had to be well under way to just pull the plug on all of us. It takes time to law that (action) out and run the numbers."

175. The foregoing allegations, read holistically, establish a strong inference of Defendants' knowledge of or their deliberate recklessness to undisclosed facts and circumstances that rendered their public statements and omissions at issue materially false or misleading, and thus support a strong inference of their scienter in making those misstatements and omissions as alleged herein.

**2. *Defendant Mahadevia Was Financially Motivated To Commit Fraud***

176. The strong inference of Defendants' scienter is further evidenced by the insider transactions reported by Defendant Mahadevia during the Class Period, involving Spero common stock, stock options, and Restricted Stock Units ("RSUs").[12] As the only Defendant who was a reporting person required to file SEC Form 4 during the entire Class Period and a comparable

[12] In Spero's 2017 Stock Incentive Plan, as Amended on August 17, 2021, RSUs were defined as follows:

> 1. Grant of Award. The Company hereby grants to the Participant an award for the number of RSUs set forth in the Restricted Stock Unit Award Grant Notice (the "Award"). Each RSU represents a contingent entitlement of the Participant to receive one share of Common Stock, on the terms and conditions and subject to all the limitations set forth herein and in the Plan, which is incorporated herein by reference. The Participant acknowledges receipt of a copy of the Plan.
>
> 2. Vesting of Award.
>
> (a) Subject to the terms and conditions set forth in this Agreement and the Plan, the Award granted hereby shall vest as set forth in the Restricted Stock Unit Award Grant Notice and is subject to the other terms and conditions of this Agreement and the Plan. On each vesting date set forth in the Restricted Stock Unit Award Grant Notice, the Participant shall be entitled to receive such number of shares of Common Stock equivalent to the number of RSUs as set forth in the Restricted Stock Unit Award Grant Notice provided that the Participant is employed or providing service to the Company or an Affiliate on such vesting date. Such shares of Common Stock shall thereafter be delivered by the Company to the Participant within five business days of the applicable vesting date and in accordance with this Agreement and the Plan.
>
> (b) Except as otherwise set forth in this Agreement, if the Participant ceases to be employed or providing services for any reason by the Company or by an Affiliate (the "Termination") prior to a vesting date set forth in the Restricted Stock Unit Award Grant Notice, then as of the date on which the Participant's employment or service terminates, all unvested RSUs shall immediately be forfeited to the Company and this Agreement shall terminate and be of no further force or effect.

period predating the Class Period, the fact that he profited from transactions at prices allegedly inflated by the fraud pled herein supports a strong inference of scienter.[13]

177. Defendant Mahadevia entered the Class Period with balances of 65,817 shares of Spero common stock and the right to acquire 1,041,457 additional shares at costs substantially below-market by way of stock options. Defendant Mahadevia's transactions during the Class Period were as follows:

| **Common Stock & Stock Option Transactions** | | | | |
|---|---|---|---|---|
| **Transaction Date** | **Emergent Purchases/ Sales** | **Shares** | **Strike Price** | **Funds Spent / Gained** |
| 09/08/2020 | Exercise of Options | 774 | $5.90 | ($4,566.60) |
| 10/13/2020 | Exercise of Options | 14,367 | $5.90 | (84,765.30) |
| 10/14/2020 | Exercise of Options | 105 | $5.90 | ($619.50) |
| 10/23/2020 | Exercise of Options | 20 | $5.90 | ($118.00) |
| 11/03/2020 | Exercise of Options | 2,137 | $5.90 | ($12,608.30) |
| 11/04/2020 | Exercise of Options | 7,370 | $5.90 | ($43,483.00) |
| 02/01/2021 | Grant of Options[14] | 179,319 | N/a | ($0) |
| 12/27/2021 | Exercise of Options | 8,000 | $5.90 | ($47,200.00) |
| 02/01/2022 | Grant of Options | 187,730 | N/a | ($0) |
| | | | | |
| | **Sub-Total Options Exercised** | **(32,773)** | **Cost** | **($193,361.00)** |
| | **Sub-Total Options Awarded** | **367,049** | **Cost** | **($0)** |
| | | | | |
| 09/08/2020 | Stock Sale | (774) | $14.25 | $11,029.70 |
| 10/13/2020 | Stock Sale | (14,367) | $14.284 | $205,212.50 |
| 10/14/2020 | Stock Sale | (105) | $14.25 | $1,496.30 |
| 10/23/2020 | Stock Sale | (20) | $14.25 | $285.00 |
| 11/3/2020 | Stock Sale | (2,137) | $14.268 | $30,489.60 |
| 11/4/2020 | Stock Sale | (7,370) | $14.428 | $106,335.10 |
| 12/27/2021 | Stock Sale | (8,000) | $14.583 | $116,664.00 |
| | | | | |
| | **Sub-Total Stock Sales** | **(32,773)** | **Gross Proceeds** | **$471,518.00** |

[13] Defendant Shukla did not join Spero until January 2021, in the middle of the Class Period. Thus, he lacks and pre-Class Period track record of insider transactions and, moreover, began his tenure with an empty cubbard from which to engage in insider transactions, even when he finally became a reporting person. As such, his trading activity, such as it is, cannot be used by either side to support or oppose an inference of scienter at the pleading stage before discovery.

[14] Per Defendant Mahadevia's February 3, 2021 Form 4 filing, the vast majority of these options had vesting dates outside the Class Period, with only 25% vesting on February 1, 2022 and the rest vesting in 36 equal monthly installments thereafter. Thus, that he did not exercise them during the alleged fraud is not an exonerating fact.

| RSU Transactions | | | | |
|---|---|---|---|---|
| **Transaction Date** | **Unit Grants / Exercises** | **Units** | **Strike Price** | **Funds Spent / Gained** |
| 08/26/2021 | Award of RSUs[15] | 78,219 | N/a | ($0) |
| 02/01/2022 | Award of RSUs[16] | 134,168 | N/a | ($0) |
| | | | | |
| **Sub-Total RSUs Awarded** | | **212,387** | **Cost** | **($0)** |
| | | | | |
| **Totals** | **Shares Purchased** | **0** | **Transaction Costs** | **($0)** |
| | **RSU Shares Gained** | **0** | **Transaction Costs** | **($0)** |
| | **Option Shares Gained** | **+32,773** | **Transaction Costs** | **($193,361.00)** |
| | **Shares Sold** | **(32,773)** | **Transaction Proceeds** | **+$471,518.00** |
| | | | **Net Gain to Defendant Mahadevia** | **+$278,157** |

178. These transactions were suspicious in amount, a fact that further supports the scienter inference. Defendant Mahadevia's $278,157 in net gains from insider transactions during the Class Period (from $$471,518 in gross insider sale proceeds), compared suspiciously against his 2020 base salary of $540,000 (***51.5%*** of that figure) and 2019 base salary of $500,000 (***55.6%*** of that figure). Furthermore, Defendant Mahadevia's sale proceeds are approximately ***163% larger*** (both gross and net) than the $169,908 in net gains (from $289,247 in gross insider sale proceeds) during the comparable pre-Class Period time.

179. These transactions were also suspicious in timing vis-à-vis the alleged fraudulent misstatements and the alleged partial corrective disclosures, as alleged herein, a fact that further supports the scienter inference.

[15] Per Defendant Mahadevia's August 30, 2021 Form 4 filing, all of these RSUs had vesting dates outside the Class Period, with vesting occurring in four equal annual installments that began on August 26, 2022. Thus, that he did not profit from them during the alleged fraud is not an exonerating fact.

[16] Per Defendant Mahadevia's February 3, 2002 Form 4 filing, all of these RSUs had vesting dates outside the Class Period, with vesting occurring in four equal annual installments that began on February 1, 2023. Thus, that he did not profit from them during the alleged fraud is not an exonerating fact.

180. Plaintiffs are pursuing a FOIA request to learn the status of any SEC investigations into Defendants' insider transactions or the other facts and circumstances at issue. The existence of any such investigation would further support the inference of scienter, and discovery into the investigation and any document productions by the Defendants to the SEC would buttress the allegations herein and be grounds for potential further amendment.

**3. *The Individual Defendants Reaped Suspicious Compensation***

181. During the Class Period, while the alleged frauds were ongoing, the Individual Defendants reaped suspicious increases in their executive compensation, ostensibly in recognition of Spero's positive performance and operating results, including the completion of the ADAPT-PO Trial and the submission and advancement of the tebipenem HBr NDA through the FDA approval process.

182. As discussed in the 2021 10-K, while Spero's annual salary increases became effective on February 1st each year, the Individual Defendant received an additional salary increase on July 1, 2021. The extra salary increase translated into anomalous and suspicious executive compensation increases in the middle of the Class Period.

183. Defendant Mahadevia's aggregate 2021 ***compensation increases totaled $80,000*** (***+14.8%***) – from his 2020 salary of $540,000 to $620,000 with an ***increase in bonus*** eligibility equivalent to an ***extra 10% of his base salary*** (*i.e.*, a target bonus opportunity of 60% of his base salary). These amounts compare suspiciously to his salaries and raises the preceding two years: (i) in 2019, his salary rose just $35,000 (from $465,000 to $500,000) with zero increase in bonus percentage eligibility (*i.e.*, a target bonus opportunity of 50% of his base salary, just like in 2018) and (ii) in 2020, his salary rose just $40,000 (from $500,000 to $540,000) with zero increase in bonus percentage eligibility in 2020 (*i.e.*, the same target bonus opportunity of 50% of his base salary as in 2019).

184. Defendant Shukla joined Spero as its CFO in January 2021, so does not have a prior track record of compensation at the company. However, he suspiciously received an off-schedule ***$35,000 raise*** (***+8.2%***) in July 2021 (from $425,000 to $460,000, both with a target bonus opportunity of 40% of his base salary), ***after just five months with the company***. Moreover, Defendant Shukla's employment agreement contains ***suspicious, defensive provisions*** entitling him to lavish severance payments should Spero terminate him without cause or should he terminate the contract "for Good Reason." These provisions included, *inter alia*, payment of his full salary for nine months post-termination and payment of his prorated target bonus, or if the termination (by either party) occurred within 90 days of certain change of control events, a lump-sum payment equal to 12 months of his salary plus a pro-rated target bonus and acceleration of his unvested equity awards at the rate of 100% (if the change of control was at least 2 years into his tenure) or 50% (if it was 12 – 24 months into his tenure) or 25% (if it was in his first 12 months).

185. These significant, suspicious executive compensation perks to Defendants Mahadevia and Shukla, not reflective of the actual results of the ADAPT-PO Trial or the true status of Spero's tebipenem HBr NDA, strongly support an inference of scienter.

#### 4. *Spero Raised Funds During The Class Period*

186. During the Class Period, Spero raised funds during the period of artificial inflation caused by the frauds alleged herein.

187. On September 11, 2020, Spero announced the pricing of an underwritten public offering of 4.785 million shares of common stock and 3.215 million shares of non-voting Series D Convertible Preferred Stock. Both types of securities were priced at $10.00. Spero announced expected gross proceeds of $80 million, before deducting underwriting discounts and commissions and other expenses. Spero also granted the underwriters a 30-day option to purchase an additional 1.2 million shares of common stock at the offering price, less underwriting discounts and

commissions. These terms were memorialized and filed with the SEC in the 9/14/2020 Prospectus Supplement and a Form 8-K filed with the SEC on September 14, 2020, which was signed by Spero interim CFO DiPalma.

188. As discussed in Spero's Q3 2020 10-Q, this offering was completed on September 15, 2020, generating aggregate net proceeds of $74.7 million after deducting underwriting discounts and commissions and offering expenses. The Q3 2020 10-Q added that on October 1, 2020, Spero issued and sold all 1.2 million shares of common stock pursuant to the underwriters' exercise of their option, which resulted in additional net proceeds of roughly $11.2 million after deducting underwriting discounts and commissions.

189. These transactions, which occurred during the fraudulent period alleged herein, evidence Spero's corporate scienter, because it was highly motivated to complete its offering at the highest possible price with the lowest possible share dilution.

**5. *Spero Reaped Unearned Windfall Government Payments***

190. As discussed *supra*, Spero reaped the benefits of a $59.7 million BARDA contract throughout the Class Period, enabling it to obtain reimbursements of expenses related to the ADAPT-PO Trial and the development of tebipenem HBr. This contract and the monies received thereunder allowed Spero to report better operating metrics, including lower net losses, than it otherwise would have generated.

191. However, as discussed herein, the ADAPT-PO trial suffered from fatal deficiencies including an insufficient evaluable patient population and trial data incapable of supporting an FDA-approvable NDA for tebipenem HBr. As such, the BARDA contract payments were not earned by Spero and it was unjustly enriched by their receipt.

192. Spero's unjust acceptance of U.S. government funds when it was unable to fulfill the important drug therapy development role for which it had been contracted further adds to the

inference of corporate scienter, particularly when viewed alongside the company's offering fundraising and the other motive allegations pled herein.

**6. *The Fraud Implicated Core Operations***

193. The fraud alleged herein implicates Spero's core operations. As discussed *supra*, Spero's development of tebipenem HBr was a part of its "core business" according to Spero's SEC filings and investor presentations during the Class Period, and it accounted for a material portion of its net loss, government contracts payments, and projected growth. Tebipenem HBr was the "most advanced" of just three product candidates that Spero was reliant upon to generate revenues and growth. Indeed, Defendants decided to reduce Spero's workforce by approximately 75% and restructure its operations to reduce operating costs after the FDA rejected the tebipenem HBr NDA. Indeed, Defendants extensively discussed Spero's development of tebipenem HBr and the likelihood of its obtaining FDA approval in Spero's SEC filings and Earning Calls throughout the Class Period, and analysts covering Spero extensively discussed the development of tebipenem HBr and its significance to Spero's financial viability in their reports.

194. In light of these facts, it is inconceivable that the Individual Defendants and executive management did not know the facts and circumstances of the fraud as alleged herein. Moreover, such knowledge is imputable to Defendants, given the implication of core operations, the Defendants' roles and status within Spero, and the facts regarding the funneling of information to them and their personal involvement in the key events and circumstances at issue, as alleged herein, including without limitation by information revealed by the CW statements.

**7. *The Individual Defendants Signed, Were Quoted In, Or SOX-Certified The Alleged Misstatements***

195. As the individuals who signed, were quoted in, or orally made the alleged false and misleading statements described herein, Defendants Mahadevia and Shukla were under an

obligation to familiarize themselves with the subject matter of those public statements and to speak truthfully. As alleged herein, they violated such duties.

196. As the individuals who SOX certified SEC filings as described *supra*, Defendants Mahadevia and Shukla were obligated to inquire and investigate, familiarize themselves with the subject matter of their SOX certifications, and reassure themselves that the certifications were accurate and that they were speaking truthfully in making them. As alleged herein, they violated such duties.

### 8. *The Fraud Violated Spero's Corporate Code of Conduct*

197. Spero's Code of Business Conduct and Ethics ("Code of Conduct"), published on its website throughout the Class Period, barred all of the misconduct detailed herein, including the concealment of the undisclosed negative facts discussed in the "Undisclosed, Material, Negative Facts" section *supra*, as revealed by the CW statements, and the insider selling and unjust self-enrichment by the Individual Defendants and Spero, as set forth in the "Additional Facts Probative of Scienter" section *supra*.

198. Spero's Code of Conduct makes clear that it is binding upon all employees:

> The ***Company requires that all employees, officers and directors comply with all laws, rules and regulations*** applicable to the Company wherever it does business. You are expected to use good judgment and common sense in seeking to comply with all applicable laws, rules and regulations and to ask for advice when you are uncertain about them.
>
> ***If you become aware of the violation of any law, rule or regulation by the Company, whether by its employees, officers, directors or any third party doing business on behalf of the Company, it is your responsibility to promptly report the matter to your supervisor or to the Chairman of the Audit Committee of the Board of Directors (the "Audit Committee"), the Chief Executive Officer or the Chief Compliance Officer***. While it is the Company's desire to address matters internally, ***nothing in this Code should discourage you from reporting any illegal activity, including any violation of the securities laws, antitrust laws, environmental laws or any other federal, state or foreign law, rule or regulation, to the appropriate regulatory authority***. Employees, officers and directors shall not discharge, demote, suspend, threaten, harass or in any other manner discriminate or

> retaliate against an employee because he or she reports any such violation, unless it is determined that the report was made with knowledge that it was false. This Code should not be construed to prohibit you from testifying, participating or otherwise assisting in any state or federal administrative, judicial or legislative proceeding or investigation.

199. The Code of Conduct also makes clear that all statements and communications must be truthful – a mandate that expressly addressed and precluded the materially false and misleading statements pled herein. Specifically, a section titled Honest and Ethical Conduct and Fair Dealing states the following:

> Employees, officers and directors should endeavor to deal honestly, ethically and fairly with the Company's suppliers, customers, competitors and employees. ***Statements regarding the Company's products and services must not be untrue, misleading, deceptive or fraudulent***. You ***must not take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts or any other unfair-dealing practice***.

200. The Code of Conduct also requires that all employees report any suspected violations or concerns regarding compliance:

> Every employee, officer and director has the responsibility to ask questions, seek guidance, report suspected violations and express concerns regarding compliance with this Code. ***Any employee, officer or director who knows or believes that any other employee or representative of the Company has engaged or is engaging in Company-related conduct that violates applicable law or this Code should report such information to his or her supervisor or to the Chairman of the Audit Committee, the Chief Executive Officer or the Chief Compliance Officer[.]***

201. Spero's Code of Conduct also prohibits employees from trading on inside information, stating:

> ***Employees, officers and directors who have material non-public information about the Company or other companies, including our suppliers and customers, as a result of their relationship with the Company are prohibited by law and Company policy from trading in securities of the Company or such other companies, as well as from communicating such information to others who might trade on the basis of that information***.

202. The Code of Conduct, generally, also expressly states the obvious – that all employees must comply with all applicable "laws, rules and regulations." This encompasses the U.S. federal securities laws, rules and regulations that Defendants violated, as alleged herein.

203. Spero's Code of Conduct makes clear that failure to comply with the standards outlined within it will result in disciplinary action, including, but not limited to, discharge:

> Failure to comply with the standards outlined in this Code will result in disciplinary action including, but not limited to, reprimands, warnings, probation or suspension without pay, demotions, reductions in salary, discharge and restitution. ***Certain violations of this Code may require the Company to refer the matter to the appropriate governmental or regulatory authorities for investigation or prosecution. Moreover, any supervisor who directs or approves of any conduct in violation of this Code, or who has knowledge of such conduct and does not immediately report it, also will be subject to disciplinary action, up to and including discharge***.

204. The forgoing provisions of Spero's Code of Conduct barred Defendants' misconduct alleged herein, including their oversight and operation of the development of tebipenem HBr in such a way as to prevent it from obtaining FDA approval and being brought to the market, their materially false and misleading public statements, and their self-enrichment through insider trading and executive compensation increases. Defendants' violation of this express corporate policy, which was in force and binding throughout the Class Period, further buttresses the inference of their scienter.

## VI. NO SAFE HARBOR

205. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Most, if not all, of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent any statements were labelled as forward-looking, they included statements of then-historical or then-present fact and there were no meaningful cautionary

statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

206. Many of the alleged statements were not accompanied by any cautionary language. Any purported cautionary language that was used was legally deficient, including because it warned only of theoretical future risks at times when those risks had already ripened due to Defendants' then-ongoing misconduct as alleged herein. Moreover, the purported cautionary language failed to adjust over time, using the same theoretical tone even after concrete changes of circumstance.

207. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable, because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Spero who knew that those statements were false when made.

208. For all these same reasons, the bespeaks caution likewise does not apply to shield Defendants from liability.

209. In addition, to the extent Defendants' statements are determined to be ones of opinion, they were materially false and misleading because (i) they were either not believed by the Defendants and were objectively false and (ii) because Spero's shareholders expected not just that Defendants believed the opinion (however irrationally), but that it fairly aligned with the information in their possession at the time. However, Defendants' statements did not fairly align with the information in their possession at the time such statements were made, and they omitted material facts about Defendants' knowledge of the true state of the facts, including, *inter alia*, the true facts concerning the development of tebipenem HBr, the likelihood it would receive FDA

approval, and the true risks and financial impacts on Spero. Specifically, it was known or knowable at the time of Defendants' statements outlined herein that the tebipenem HBr ADAPT-PO Trial had serious deficiencies to such an extent that its ability to obtain FDA approval was impossibly compromised. Those true facts were known to Defendants or recklessly disregarded by them and conflicted with what a reasonable investor would take from Defendants' statements.

## VII. THE CLAIMS ARE TIMELY

210. The claims set forth herein were timely filed.

211. The market was not arguably aware until March 31, 2022 at the earliest, that credible allegations existed to the effect that Spero misrepresented and failed to disclose material facts about its business and operations, particularly in regards to the development of tebipenem HBr and likelihood of receiving FDA approval.

212. It was also not until March 31, 2022 that Plaintiffs were first presented with any credible evidence that Defendants had made materially false and misleading statements to investors during the Class Period. In the absence of publicly available information prior to then suggesting that Spero's pronouncements in its SEC filings and other public statements during the Class Period were materially false and/or misleading, Plaintiffs were not under any duty to inquire as to the truthfulness of Spero's public statements. Therefore, Plaintiffs' duty in that regard arose no earlier than May 3, 2022.

213. Prior to March 31, 2022, Plaintiffs and Class members could not have been on any inquiry notice of possible claims under the Securities Exchange Act. Even assuming this early date for inquiry notice, Plaintiffs' Securities Exchange Act claims against Defendants were brought within two years. Therefore, Plaintiffs have complied with the requirements of 28 U.S.C. §1658(b).

## VIII. LOSS CAUSATION/ECONOMIC LOSS

214. The market for Spero shares was open, well-developed, and efficient at all relevant times. During the Class Period, as detailed herein, Defendants engaged in a course of conduct and a scheme to deceive the market that artificially inflated Spero shares and operated as a fraud or deceit on Class Period purchasers of Spero shares by misrepresenting the material facts set forth herein. As detailed above, when Defendants' prior misrepresentations became known to the public through a series of partial corrective disclosures, the price of Spero shares fell precipitously, as the prior artificial inflation came out. As a result of their purchases of Spero shares during the Class Period, Plaintiffs and the other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws.

215. Defendants' allegedly unlawful conduct caused the losses incurred by Plaintiffs and the Class. The market for Spero's common stock was open, well developed, and efficient at all relevant times. Throughout the Class Period, Spero's common stock traded at artificially inflated prices as a direct result of Defendants' materially misleading statements and omissions of material fact, which were widely disseminated to the securities market, investment analysts, and the investing public. Plaintiffs and other Class members purchased or otherwise acquired Spero common stock relying upon the integrity of the market price for Spero's common stock and market information relating to Spero and have been damaged thereby.

216. During the Class Period, Defendants presented a misleading picture of Spero's financial condition, revenues, growth, performance, and business prospects, including without limitation the contributions and impacts arising from the development of tebipenem HBr and the likelihood it would receive FDA approval. Defendants' false and misleading statements had the intended effect and caused Spero shares to trade at artificially inflated prices throughout the Class Period and until the truth was revealed to the market.

217. As detailed herein, the price of Spero shares sharply dropped, on high volume, in response to each of the following partially corrective disclosures, alleged herein: (a) Spero's press release and SEC filing on March 31, 2022, and (b) Spero's press release and SEC filing on May 3, 2022. Each of the related stock drops partially removed inflation from the price of Spero shares, causing real economic loss to investors who had purchased Spero shares during the Class Period.

218. These declines were a direct and proximate result of the nature and extent of Defendants' fraud being revealed to investors and the market. The timing and magnitude of the price declines in Spero shares negate any inference that the loss suffered by Plaintiffs and the other Class members was caused by changed market conditions, macroeconomic factors, or Spero-specific facts unrelated to Defendants' fraudulent conduct.

219. The economic loss, *i.e.*, damages, suffered by Plaintiffs and other Class members was a direct and proximate result of Defendants' fraudulent scheme to artificially inflate Spero's share price and the subsequent significant declines in the value of Spero shares when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

## IX. PRESUMPTION OF RELIANCE

220. At all times, the market for Spero shares was an efficient market, supporting a presumption of reliance under the fraud-on-the-market doctrine, for the following reasons, among others:

(a) Spero met the requirements for listing and was listed and actively traded on NASDAQ, a highly efficient and automated market, under the ticker symbol "SPRO";

(b) Spero had approximately 27,187,489 shares outstanding as of October 29, 2020, such that its stock was liquid. During the Class Period, numerous shares of Spero stock were traded on a daily basis, with moderate to heavy volume, demonstrating an active and broad market for Spero stock and permitting a strong presumption of an efficient market;

(c) As a regulated issuer, Spero filed periodic public reports with the SEC;

(d) Spero regularly communicated with public investors via established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(e) Spero was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period; and

(f) Unexpected material news about Spero was rapidly reflected and incorporated into Spero's stock price during the Class Period.

221. As a result of the foregoing, the market for Spero stock promptly digested current information regarding Spero from all publicly available sources and reflected such information in the prices of the stock. Under these circumstances, all purchasers of Spero stock during the Class Period suffered similar injury through their purchase of Spero stock at artificially inflated prices and a presumption of reliance applies.

222. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

## X. PLAINTIFFS' CLASS ACTION ALLEGATIONS

223. Plaintiffs bring this federal securities action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class (the "Class") of all persons and entities who purchased or otherwise acquired the common stock of Spero (NASDAQ:SPRO) between

September 8, 2020 and May 2, 2022, both dates inclusive (the "Class Period"), seeking to pursue remedies against Defendants Spero, Mahadevia and Shukla for violations of the federal securities laws under Exchange Act §§10(b) and 20(a) and SEC Rule 10b-5.

224. Excluded from the Class are Defendants herein, their family members and their affiliates, and any entities in which they owned a controlling interest, the officers and directors of Spero at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns.

225. The Class members are so numerous that joinder of all members is impracticable. Throughout the Class Period, Spero stock was actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Spero or its transfer agent and may be notified of the pendency of this action by mail, with Class members not so identified being notified through publication notice, using forms of notice similar to that customarily used in securities class actions.

226. Plaintiffs' claims are typical of the claims of the Class members, as all Class members are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

227. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

228. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Spero, including without limitation as regarded the development of tebipenem HBr and the likelihood of it receiving FDA approval;
- whether the Individual Defendants caused Spero to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Spero stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

229. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

230. As alleged herein, Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine inasmuch as Defendants made public misrepresentations or failed to disclose material facts during the Class Period; the misrepresentations and omissions were material and would tend to induce a reasonable investor to

misjudge the value of Spero's common stock; and Plaintiffs and the Class members purchased or otherwise acquired Spero common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were fully disclosed, without knowledge of the omitted or misrepresented facts.

## XI. CLAIMS FOR RELIEF

### COUNT I

**(Against All Defendants For Violation Of Exchange Act Section 10(b) and Rule 10b-5 Promulgated Thereunder)**

231. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

232. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

233. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other Class members; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such schemes were intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Spero securities; and (iii) cause Plaintiffs and the other Class members to purchase or otherwise acquire Spero common stock and options at artificially inflated prices. In furtherance of this unlawful

scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

234. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases, teleconferences with analysts and investors, and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Spero securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Spero's finances and business prospects, including without limitation as regarded the development of tebipenem HBr and the likelihood of it receiving FDA approval.

235. Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein, including by virtue of their positions at Spero, and intended thereby to deceive Plaintiffs and the other Class members, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

236. Defendants were personally motivated to make false statements and omit material information necessary to make the statements not misleading in order to personally benefit from the sale of Spero securities.

237. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. Defendants' first-hand knowledge is alleged herein. Moreover, as the senior managers and/or directors of Spero, who among other things oversaw the development of tebipenem HBr and interacted directly with the FDA regarding its approval, the Individual Defendants had knowledge of the details of Spero's operations, business, and internal affairs, including without limitation those regarding tebipenem HBr and the likelihood of it receiving FDA approval.

238. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Spero. As officers and/or directors of a publicly held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Spero's businesses, operations, financial condition, and prospects, including without limitation as regarded the development of tebipenem HBr and the likelihood of it receiving FDA approval. As a result of the dissemination of the false and misleading reports, releases and public statements alleged herein, the market price of Spero securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Spero's business, operations, and financial condition concealed by Defendants, including without limitation those regarding tebipenem HBr and the likelihood of it receiving FDA approval, Plaintiffs and the other Class members purchased or otherwise acquired Spero's common stock at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

239. During the Class Period, Spero securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Spero common stock at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other Class members known the truth, they would not have purchased or otherwise acquired said shares, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Spero stock was substantially lower than the prices paid by Plaintiffs and the other Class members. The market price of Spero securities declined sharply upon public disclosures of the fraud alleged herein, to the injury of Plaintiffs and Class members.

240. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

241. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other Class members suffered damages in connection with their respective purchases, acquisitions, and sales of Spero's common stock during the Class Period, upon the disclosures that Spero had been disseminating materially false or misleading misstatements and omissions to the investing public.

**COUNT II**

**(Against the Individual Defendants For Violation of Section 20(a) of the Exchange Act)**

242. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

243. During the Class Period, the Individual Defendants participated in the operation and management of Spero, and conducted and participated, directly and indirectly, in the conduct of Spero's business affairs. Because of their senior positions, they knew the adverse non-public information about Spero's business, operations, finances, and prospects, including without limitation the adverse non-public information about tebipenem HBr and the likelihood of it receiving FDA approval.

244. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Spero's business, operations, financial condition, results of operations, and prospects, including without limitation as regarded the development of tebipenem HBr and the likelihood of it receiving FDA approval, and to correct promptly any public statements issued by Spero which had become materially false or misleading.

245. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, SEC filings, and other public statements that Spero disseminated in the marketplace during the Class Period concerning its business, operations, financial condition, results of operations, and prospects, including without limitation as regarded the development of tebipenem HBr and the likelihood of it receiving FDA approval. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Spero to engage in the wrongful acts complained of herein. The

Individual Defendants, therefore, were "controlling persons" of Spero within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged herein that artificially inflated the market price of Spero stock.

246. Each of the Individual Defendants, therefore, acted as a controlling person of Spero. By reason of their senior management positions and/or being directors of Spero, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Spero to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations and business of Spero and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other Class members.

247. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Spero.

## XII. PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs hereby demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Fed. R. Civ. P. 23 and certifying Plaintiffs as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other Class members prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

## XIII. DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

Dated: December 5, 2022

Respectfully submitted,

**POMERANTZ LLP**

By: /s/*Matthew L. Tuccillo*
Jeremy A. Lieberman
Matthew L. Tuccillo
Jennifer Banner Sobers
Brandon M. Cordovi
(*pro hac vice* application forthcoming)
600 Third Avenue, 20th Floor
New York, NY 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
jalieberman@pomlaw.com
mltuccillo@pomlaw.com
jbsobers@pomlaw.com
bcordovi@pomlaw.com

***Lead Counsel***

**THE SCHALL FIRM**

Brian Schall
(*pro hac vice* application forthcoming)
2049 Century Park East, Ste. 2460
Los Angeles, CA 90067
Telephone: 310-301-3335
brian@schallfirm.com

***Additional Counsel for Lead Plaintiff Memon***

**GLANCY PRONGAY & MURRAY LLP**

Charles H. Linehan
(*pro hac vice* application forthcoming)
1925 Century Park East
Suite 2100
Los Angeles, CA 90067
Telephone: (310) 201-9150
Facsimile: (310) 432-1495
clinehan@glancylaw.com

***Additional Counsel for Plaintiff Saad***

**CERTIFICATION PURSUANT**
**TO FEDERAL SECURITIES LAWS**

1. I, Kashif Memon, make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

2. I have reviewed the initial complaint against Spero Therapeutics, Inc. ("Spero" or the "Company") and authorize the filing of an amended complaint on my behalf.

3. I did not purchase or acquire Spero securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.

4. I am willing to serve as a representative party on behalf of a Class of investors who purchased or otherwise acquired Spero securities during the class period, as may be expanded, including providing testimony at deposition and trial, if necessary. I understand that the Court had the authority to select the most adequate lead plaintiff in this action and appointed me.

5. The attached sheet lists all of my transactions in Spero securities during the Class Period as specified in the amended complaint.

6. During the three-year period preceding the date on which this Certification is signed, I have not served or sought to serve as a representative party on behalf of a class under the federal securities laws.

7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the amended complaint, beyond my *pro rata* share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

8. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

**Executed** 11/30/2022 **(Date)**

DocuSigned by:
Kashif Memon
8382555018124D8...

**(Signature)**

**Kashif Memon**

**Spero Therapeutics, Inc. (SPRO)** **Kashif Memon**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Purchase | 9/10/2020 | 200 | $12.5900 |
| Purchase | 9/10/2020 | 100 | $10.8600 |
| Purchase | 9/10/2020 | 100 | $12.3600 |
| Purchase | 9/11/2020 | 100 | $9.9100 |
| Purchase | 9/11/2020 | 100 | $9.9100 |
| Purchase | 9/11/2020 | 100 | $9.9100 |
| Purchase | 9/23/2020 | 100 | $9.5648 |
| Purchase | 9/28/2020 | 50 | $10.1000 |
| Purchase | 9/28/2020 | 40 | $10.2100 |
| Purchase | 10/1/2020 | 250 | $11.1600 |
| Purchase | 10/1/2020 | 100 | $11.4122 |
| Purchase | 10/6/2020 | 400 | $12.5000 |
| Purchase | 10/6/2020 | 100 | $12.1850 |
| Purchase | 10/6/2020 | 100 | $12.2200 |
| Purchase | 10/6/2020 | 100 | $12.2200 |
| Purchase | 10/8/2020 | 495 | $13.5300 |
| Purchase | 10/8/2020 | 100 | $12.9000 |
| Purchase | 10/8/2020 | 5 | $13.2000 |
| Purchase | 10/9/2020 | 25 | $13.3100 |
| Purchase | 10/14/2020 | 200 | $13.3200 |
| Purchase | 10/14/2020 | 100 | $14.0800 |
| Purchase | 10/15/2020 | 100 | $13.2650 |
| Purchase | 10/16/2020 | 100 | $12.9400 |
| Purchase | 10/29/2020 | 100 | $13.8000 |
| Purchase | 10/30/2020 | 500 | $13.0699 |
| Purchase | 10/30/2020 | 500 | $13.0950 |
| Purchase | 11/2/2020 | 1,000 | $12.8900 |
| Purchase | 11/2/2020 | 1,000 | $12.9485 |
| Purchase | 11/3/2020 | 1,000 | $13.9200 |
| Purchase | 11/3/2020 | 500 | $13.8899 |
| Purchase | 11/3/2020 | 500 | $13.8200 |
| Purchase | 11/3/2020 | 500 | $13.9250 |
| Purchase | 11/3/2020 | 400 | $13.8600 |
| Purchase | 11/3/2020 | 250 | $14.0700 |
| Purchase | 11/3/2020 | 100 | $13.9000 |
| Purchase | 11/3/2020 | 1,000 | $13.9200 |
| Purchase | 11/3/2020 | 500 | $13.8200 |
| Purchase | 11/3/2020 | 500 | $13.9250 |
| Purchase | 11/4/2020 | 980 | $14.1600 |
| Purchase | 11/4/2020 | 100 | $13.7400 |
| Purchase | 11/4/2020 | 100 | $14.1050 |
| Purchase | 11/4/2020 | 20 | $14.1500 |
| Purchase | 11/12/2020 | 1,000 | $14.5000 |
| Purchase | 11/12/2020 | 302 | $14.5800 |
| Purchase | 11/12/2020 | 196 | $14.6199 |

**Spero Therapeutics, Inc. (SPRO)** **Kashif Memon**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Purchase | 11/12/2020 | 102 | $14.6100 |
| Purchase | 11/12/2020 | 100 | $14.5300 |
| Purchase | 11/12/2020 | 100 | $14.6095 |
| Purchase | 11/12/2020 | 100 | $14.7500 |
| Purchase | 11/12/2020 | 100 | $14.7500 |
| Purchase | 11/16/2020 | 500 | $14.3599 |
| Purchase | 11/17/2020 | 1,000 | $14.7000 |
| Purchase | 11/17/2020 | 1,000 | $14.7500 |
| Purchase | 11/18/2020 | 500 | $14.9000 |
| Purchase | 11/19/2020 | 1,000 | $14.6900 |
| Purchase | 11/19/2020 | 100 | $14.8500 |
| Purchase | 11/19/2020 | 10 | $14.5000 |
| Purchase | 11/23/2020 | 500 | $15.8000 |
| Purchase | 11/23/2020 | 500 | $15.9500 |
| Purchase | 11/23/2020 | 500 | $16.0000 |
| Purchase | 11/23/2020 | 100 | $15.9000 |
| Purchase | 11/23/2020 | 100 | $15.9500 |
| Purchase | 11/23/2020 | 100 | $15.9700 |
| Purchase | 11/24/2020 | 100 | $15.4600 |
| Purchase | 11/30/2020 | 1,000 | $16.3000 |
| Purchase | 11/30/2020 | 1,000 | $16.7300 |
| Purchase | 12/3/2020 | 1,000 | $17.5700 |
| Purchase | 12/3/2020 | 15 | $17.6500 |
| Purchase | 12/4/2020 | 399 | $17.3000 |
| Purchase | 12/10/2020 | 700 | $16.9850 |
| Purchase | 12/10/2020 | 200 | $16.9500 |
| Purchase | 12/10/2020 | 200 | $16.9825 |
| Purchase | 12/10/2020 | 100 | $16.9840 |
| Purchase | 12/15/2020 | 1,000 | $17.1500 |
| Purchase | 12/15/2020 | 1,000 | $17.2800 |
| Purchase | 12/15/2020 | 1,000 | $17.4000 |
| Purchase | 12/15/2020 | 1,000 | $17.6000 |
| Purchase | 12/15/2020 | 400 | $17.2000 |
| Purchase | 12/17/2020 | 2,000 | $18.6000 |
| Purchase | 12/17/2020 | 1,000 | $18.9000 |
| Purchase | 12/17/2020 | 100 | $18.7000 |
| Purchase | 12/18/2020 | 1,000 | $18.5500 |
| Purchase | 12/18/2020 | 1,000 | $18.6000 |
| Purchase | 12/18/2020 | 500 | $18.4000 |
| Purchase | 12/18/2020 | 300 | $17.8000 |
| Purchase | 12/18/2020 | 200 | $18.2000 |
| Purchase | 12/18/2020 | 100 | $17.8300 |
| Purchase | 12/18/2020 | 100 | $18.3000 |
| Purchase | 12/22/2020 | 1,000 | $21.0000 |
| Purchase | 12/23/2020 | 1,000 | $21.5000 |

**Spero Therapeutics, Inc. (SPRO)** **Kashif Memon**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Purchase | 12/23/2020 | 100 | $21.1700 |
| Purchase | 12/30/2020 | 1,000 | $20.4700 |
| Purchase | 12/31/2020 | 500 | $18.7499 |
| Purchase | 12/31/2020 | 500 | $19.4100 |
| Purchase | 12/31/2020 | 500 | $20.1000 |
| Purchase | 1/4/2021 | 250 | $17.9100 |
| Purchase | 1/4/2021 | 250 | $18.4937 |
| Purchase | 1/5/2021 | 500 | $16.8100 |
| Purchase | 1/8/2021 | 250 | $16.0500 |
| Purchase | 1/11/2021 | 250 | $16.0000 |
| Purchase | 1/26/2021 | 20 | $18.8000 |
| Purchase | 1/26/2021 | 13 | $18.6600 |
| Purchase | 1/27/2021 | 2,000 | $18.6600 |
| Purchase | 1/27/2021 | 1,000 | $18.8500 |
| Purchase | 1/27/2021 | 500 | $17.9396 |
| Purchase | 1/28/2021 | 500 | $17.8500 |
| Purchase | 2/2/2021 | 1,000 | $18.9200 |
| Purchase | 2/3/2021 | 100 | $18.7700 |
| Purchase | 2/5/2021 | 2,000 | $16.9500 |
| Purchase | 2/5/2021 | 1,000 | $16.0000 |
| Purchase | 2/5/2021 | 1,000 | $16.2500 |
| Purchase | 2/5/2021 | 100 | $14.7000 |
| Purchase | 2/5/2021 | 100 | $14.9300 |
| Purchase | 2/5/2021 | 100 | $15.5000 |
| Purchase | 2/5/2021 | 100 | $15.8000 |
| Purchase | 2/5/2021 | 100 | $15.8000 |
| Purchase | 2/5/2021 | 100 | $16.0000 |
| Purchase | 2/5/2021 | 100 | $16.2000 |
| Purchase | 2/11/2021 | 1,000 | $19.8000 |
| Purchase | 2/11/2021 | 1,000 | $20.1100 |
| Purchase | 2/11/2021 | 400 | $19.7600 |
| Purchase | 2/11/2021 | 100 | $19.7450 |
| Purchase | 2/18/2021 | 1,000 | $20.1584 |
| Purchase | 2/18/2021 | 390 | $19.9900 |
| Purchase | 2/22/2021 | 1,000 | $20.0066 |
| Purchase | 2/22/2021 | 110 | $19.9900 |
| Purchase | 2/23/2021 | 400 | $18.2600 |
| Purchase | 2/23/2021 | 250 | $18.1900 |
| Purchase | 2/25/2021 | 1,000 | $18.8313 |
| Purchase | 2/25/2021 | 250 | $18.3974 |
| Purchase | 2/25/2021 | 100 | $18.3000 |
| Purchase | 2/26/2021 | 100 | $18.0000 |
| Purchase | 3/2/2021 | 200 | $18.0500 |
| Purchase | 3/3/2021 | 100 | $17.3200 |
| Purchase | 3/4/2021 | 100 | $16.0000 |

**Spero Therapeutics, Inc. (SPRO)** **Kashif Memon**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Purchase | 3/4/2021 | 100 | $16.1700 |
| Purchase | 3/4/2021 | 100 | $16.3299 |
| Purchase | 3/4/2021 | 30 | $15.9800 |
| Purchase | 3/5/2021 | 100 | $15.6600 |
| Purchase | 3/19/2021 | 200 | $15.7400 |
| Purchase | 3/23/2021 | 500 | $14.4700 |
| Purchase | 3/24/2021 | 100 | $13.9200 |
| Purchase | 3/24/2021 | 65 | $13.9200 |
| Purchase | 3/26/2021 | 22 | $13.8100 |
| Purchase | 3/29/2021 | 100 | $13.2200 |
| Purchase | 3/29/2021 | 100 | $13.5789 |
| Purchase | 4/7/2021 | 200 | $12.8491 |
| Purchase | 4/7/2021 | 98 | $12.8300 |
| Purchase | 4/9/2021 | 500 | $12.8300 |
| Purchase | 4/9/2021 | 500 | $13.3900 |
| Purchase | 4/12/2021 | 200 | $13.1600 |
| Purchase | 4/12/2021 | 100 | $12.6799 |
| Purchase | 4/13/2021 | 100 | $12.6900 |
| Purchase | 4/19/2021 | 100 | $12.5099 |
| Purchase | 5/5/2021 | 100 | $12.9273 |
| Purchase | 5/6/2021 | 100 | $12.5600 |
| Purchase | 5/10/2021 | 100 | $12.5300 |
| Purchase | 6/18/2021 | 300 | $14.8417 |
| Purchase | 6/21/2021 | 380 | $14.2372 |
| Purchase | 6/22/2021 | 100 | $13.8500 |
| Purchase | 6/29/2021 | 1,000 | $14.0000 |
| Purchase | 6/30/2021 | 588 | $19.1000 |
| Purchase | 6/30/2021 | 520 | $17.2000 |
| Purchase | 6/30/2021 | 480 | $17.4500 |
| Purchase | 6/30/2021 | 468 | $16.5000 |
| Purchase | 6/30/2021 | 402 | $19.4400 |
| Purchase | 6/30/2021 | 10 | $19.4000 |
| Purchase | 7/1/2021 | 1,000 | $17.0000 |
| Purchase | 7/1/2021 | 1,000 | $17.5000 |
| Purchase | 7/1/2021 | 1,000 | $17.5500 |
| Purchase | 7/1/2021 | 730 | $16.8500 |
| Purchase | 7/1/2021 | 300 | $15.6000 |
| Purchase | 7/1/2021 | 300 | $15.9399 |
| Purchase | 7/1/2021 | 200 | $15.6800 |
| Purchase | 7/1/2021 | 200 | $15.8500 |
| Purchase | 7/1/2021 | 200 | $15.9600 |
| Purchase | 7/1/2021 | 100 | $15.7700 |
| Purchase | 7/1/2021 | 100 | $15.9446 |
| Purchase | 7/1/2021 | 100 | $15.9899 |
| Purchase | 7/1/2021 | 100 | $16.7700 |

**Spero Therapeutics, Inc. (SPRO)** **Kashif Memon**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Purchase | 7/1/2021 | 70 | $16.8100 |
| Purchase | 7/1/2021 | 50 | $16.7300 |
| Purchase | 7/1/2021 | 50 | $16.7600 |
| Purchase | 7/2/2021 | 400 | $15.7900 |
| Purchase | 7/2/2021 | 300 | $15.8500 |
| Purchase | 7/2/2021 | 300 | $15.9000 |
| Purchase | 7/2/2021 | 100 | $15.8276 |
| Purchase | 7/6/2021 | 500 | $15.2000 |
| Purchase | 7/6/2021 | 300 | $15.3000 |
| Purchase | 7/6/2021 | 200 | $15.2000 |
| Purchase | 7/7/2021 | 400 | $15.0100 |
| Purchase | 7/7/2021 | 100 | $14.9100 |
| Purchase | 7/12/2021 | 200 | $14.9500 |
| Purchase | 7/13/2021 | 200 | $14.3599 |
| Purchase | 7/13/2021 | 100 | $14.2200 |
| Purchase | 7/15/2021 | 200 | $14.1200 |
| Purchase | 7/30/2021 | 100 | $13.3300 |
| Purchase | 8/16/2021 | 100 | $13.1092 |
| Purchase | 8/19/2021 | 200 | $13.3000 |
| Purchase | 9/1/2021 | 200 | $17.3800 |
| Purchase | 9/1/2021 | 200 | $17.6199 |
| Purchase | 9/3/2021 | 300 | $17.6800 |
| Purchase | 9/3/2021 | 200 | $17.8627 |
| Purchase | 9/3/2021 | 100 | $17.6799 |
| Purchase | 9/3/2021 | 100 | $17.6800 |
| Purchase | 9/3/2021 | 100 | $17.6900 |
| Purchase | 9/3/2021 | 100 | $17.7999 |
| Purchase | 9/3/2021 | 100 | $17.8000 |
| Purchase | 9/3/2021 | 100 | $18.1100 |
| Purchase | 9/9/2021 | 2,000 | $18.6000 |
| Purchase | 9/9/2021 | 494 | $18.6500 |
| Purchase | 9/9/2021 | 440 | $18.6477 |
| Purchase | 9/9/2021 | 66 | $18.6050 |
| Purchase | 9/13/2021 | 1,000 | $18.5676 |
| Purchase | 9/13/2021 | 500 | $18.6299 |
| Purchase | 9/15/2021 | 1,000 | $18.5400 |
| Purchase | 9/15/2021 | 1,000 | $18.5468 |
| Purchase | 9/16/2021 | 1,000 | $18.7000 |
| Purchase | 9/20/2021 | 1,000 | $18.5500 |
| Purchase | 9/20/2021 | 500 | $18.2000 |
| Purchase | 9/24/2021 | 2,000 | $19.2500 |
| Purchase | 9/24/2021 | 500 | $18.8700 |
| Purchase | 9/24/2021 | 500 | $18.9299 |
| Purchase | 9/24/2021 | 100 | $18.6600 |
| Purchase | 9/24/2021 | 100 | $18.6809 |

**Spero Therapeutics, Inc. (SPRO)** **Kashif Memon**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Purchase | 9/24/2021 | 100 | $18.6809 |
| Purchase | 9/24/2021 | 100 | $18.6883 |
| Purchase | 9/24/2021 | 100 | $18.6900 |
| Purchase | 9/24/2021 | 100 | $18.6900 |
| Purchase | 9/24/2021 | 100 | $18.8800 |
| Purchase | 9/24/2021 | 100 | $18.9214 |
| Purchase | 9/24/2021 | 100 | $18.9214 |
| Purchase | 9/27/2021 | 1,000 | $19.3550 |
| Purchase | 9/28/2021 | 2,000 | $19.2200 |
| Purchase | 9/28/2021 | 801 | $19.0100 |
| Purchase | 9/28/2021 | 100 | $19.0100 |
| Purchase | 9/29/2021 | 1,000 | $18.6100 |
| Purchase | 9/29/2021 | 1,000 | $18.7700 |
| Purchase | 9/29/2021 | 1,000 | $18.7724 |
| Purchase | 9/29/2021 | 400 | $18.4616 |
| Purchase | 9/29/2021 | 300 | $18.3000 |
| Purchase | 9/29/2021 | 300 | $18.4799 |
| Purchase | 9/29/2021 | 272 | $18.2800 |
| Purchase | 9/29/2021 | 100 | $18.0000 |
| Purchase | 9/29/2021 | 100 | $18.0500 |
| Purchase | 9/29/2021 | 100 | $18.1000 |
| Purchase | 9/29/2021 | 100 | $18.1500 |
| Purchase | 9/29/2021 | 100 | $18.1800 |
| Purchase | 9/29/2021 | 100 | $18.2600 |
| Purchase | 9/29/2021 | 100 | $18.2999 |
| Purchase | 9/29/2021 | 100 | $18.4599 |
| Purchase | 9/29/2021 | 50 | $17.9500 |
| Purchase | 10/1/2021 | 1,000 | $16.9099 |
| Purchase | 10/1/2021 | 100 | $17.1599 |
| Purchase | 10/1/2021 | 100 | $17.1645 |
| Purchase | 10/6/2021 | 1,000 | $17.6185 |
| Purchase | 10/6/2021 | 200 | $17.1999 |
| Purchase | 10/6/2021 | 100 | $17.3200 |
| Purchase | 10/6/2021 | 100 | $17.3800 |
| Purchase | 10/6/2021 | 100 | $17.4050 |
| Purchase | 10/6/2021 | 100 | $17.4299 |
| Purchase | 10/6/2021 | 100 | $17.5100 |
| Purchase | 10/6/2021 | 100 | $17.5700 |
| Purchase | 10/6/2021 | 1 | $17.2000 |
| Purchase | 10/7/2021 | 200 | $16.8100 |
| Purchase | 10/7/2021 | 200 | $16.8100 |
| Purchase | 10/21/2021 | 500 | $16.9200 |
| Purchase | 10/21/2021 | 100 | $16.8200 |
| Purchase | 10/22/2021 | 100 | $16.4100 |
| Purchase | 11/9/2021 | 250 | $16.5099 |

**Spero Therapeutics, Inc. (SPRO)** **Kashif Memon**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Purchase | 11/9/2021 | 100 | $16.5299 |
| Purchase | 11/10/2021 | 100 | $16.7000 |
| Purchase | 11/10/2021 | 100 | $16.7911 |
| Purchase | 11/17/2021 | 400 | $16.2000 |
| Purchase | 11/17/2021 | 100 | $16.0000 |
| Purchase | 11/17/2021 | 100 | $16.2200 |
| Purchase | 11/23/2021 | 500 | $15.3585 |
| Purchase | 11/23/2021 | 100 | $15.3699 |
| Purchase | 11/23/2021 | 100 | $15.3699 |
| Purchase | 11/23/2021 | 100 | $15.3699 |
| Purchase | 11/29/2021 | 100 | $15.1500 |
| Purchase | 11/30/2021 | 100 | $14.2000 |
| Purchase | 12/3/2021 | 100 | $13.5099 |
| Purchase | 2/2/2022 | 100 | $11.2900 |
| Purchase | 2/3/2022 | 300 | $10.6690 |
| Purchase | 2/3/2022 | 100 | $10.7073 |
| Purchase | 2/4/2022 | 200 | $10.9900 |
| Purchase | 2/15/2022 | 500 | $9.7883 |
| Purchase | 2/15/2022 | 200 | $9.7999 |
| Purchase | 2/16/2022 | 99 | $9.7200 |
| Purchase | 2/17/2022 | 200 | $9.4900 |
| Purchase | 2/23/2022 | 125 | $8.7000 |
| Purchase | 3/3/2022 | 100 | $8.9499 |
| Purchase | 3/10/2022 | 300 | $8.5599 |
| Purchase | 3/10/2022 | 100 | $8.5599 |
| Purchase | 3/14/2022 | 100 | $7.8689 |
| Purchase | 3/14/2022 | 100 | $7.8799 |
| Purchase | 3/16/2022 | 100 | $7.7599 |
| Purchase | 3/31/2022 | 1,000 | $7.0000 |
| Purchase | 3/31/2022 | 500 | $6.7400 |
| Purchase | 4/1/2022 | 1,000 | $6.6099 |
| Purchase | 4/1/2022 | 1,000 | $6.6699 |
| Purchase | 4/1/2022 | 100 | $6.6098 |
| Purchase | 4/12/2022 | 1,000 | $6.7900 |
| Purchase | 4/14/2022 | 1,000 | $6.3145 |
| Sale | 9/8/2020 | (500) | $13.2100 |
| Sale | 9/8/2020 | (1,000) | $13.2000 |
| Sale | 9/30/2020 | (940) | $11.2631 |
| Sale | 10/2/2020 | (305) | $12.0000 |
| Sale | 10/5/2020 | (45) | $12.5700 |
| Sale | 10/7/2020 | (100) | $13.0700 |
| Sale | 10/7/2020 | (600) | $12.8250 |
| Sale | 10/9/2020 | (99) | $13.5900 |
| Sale | 10/9/2020 | (500) | $13.6000 |
| Sale | 10/22/2020 | (526) | $13.9317 |

**Spero Therapeutics, Inc. (SPRO)** **Kashif Memon**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Sale | 11/2/2020 | (100) | $13.3300 |
| Sale | 11/2/2020 | (100) | $13.3600 |
| Sale | 11/2/2020 | (900) | $13.3200 |
| Sale | 11/2/2020 | (2,000) | $13.1000 |
| Sale | 11/2/2020 | (2,000) | $13.0501 |
| Sale | 11/2/2020 | (2,000) | $13.0501 |
| Sale | 11/10/2020 | (400) | $14.1601 |
| Sale | 11/10/2020 | (600) | $14.1700 |
| Sale | 11/10/2020 | (1,450) | $14.2200 |
| Sale | 11/13/2020 | (2,000) | $14.7500 |
| Sale | 11/16/2020 | (500) | $14.9000 |
| Sale | 11/17/2020 | (1,000) | $14.9900 |
| Sale | 11/18/2020 | (1,000) | $15.2000 |
| Sale | 11/20/2020 | (100) | $14.9838 |
| Sale | 11/20/2020 | (102) | $15.0250 |
| Sale | 11/20/2020 | (1,408) | $14.9840 |
| Sale | 11/23/2020 | (800) | $16.1500 |
| Sale | 11/27/2020 | (100) | $16.3500 |
| Sale | 11/27/2020 | (1,000) | $16.2000 |
| Sale | 12/1/2020 | (2,000) | $17.0000 |
| Sale | 12/14/2020 | (100) | $17.8000 |
| Sale | 12/14/2020 | (100) | $17.8401 |
| Sale | 12/14/2020 | (100) | $17.8600 |
| Sale | 12/14/2020 | (120) | $17.8100 |
| Sale | 12/14/2020 | (200) | $17.8200 |
| Sale | 12/14/2020 | (1,994) | $17.7800 |
| Sale | 12/15/2020 | (2) | $17.9900 |
| Sale | 12/16/2020 | (48) | $17.9900 |
| Sale | 12/16/2020 | (350) | $17.9500 |
| Sale | 12/16/2020 | (1,000) | $17.8000 |
| Sale | 12/16/2020 | (1,000) | $17.9900 |
| Sale | 12/16/2020 | (1,000) | $18.0500 |
| Sale | 12/16/2020 | (1,000) | $18.1000 |
| Sale | 12/17/2020 | (1,000) | $18.9900 |
| Sale | 12/17/2020 | (1,000) | $19.1500 |
| Sale | 12/21/2020 | (2,000) | $19.1000 |
| Sale | 12/21/2020 | (2,300) | $19.0500 |
| Sale | 12/22/2020 | (100) | $21.9550 |
| Sale | 12/22/2020 | (900) | $21.9850 |
| Sale | 12/23/2020 | (564) | $22.5000 |
| Sale | 12/24/2020 | (200) | $22.3000 |
| Sale | 12/24/2020 | (200) | $22.4000 |
| Sale | 12/28/2020 | (36) | $22.3500 |
| Sale | 12/28/2020 | (100) | $22.4000 |
| Sale | 1/26/2021 | (1,000) | $19.0000 |

**Spero Therapeutics, Inc. (SPRO)** **Kashif Memon**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Sale | 1/26/2021 | (1,000) | $19.2100 |
| Sale | 1/26/2021 | (1,000) | $19.2500 |
| Sale | 1/26/2021 | (1,000) | $19.3300 |
| Sale | 2/1/2021 | (33) | $19.3000 |
| Sale | 2/1/2021 | (1,000) | $19.0200 |
| Sale | 2/1/2021 | (1,000) | $19.2000 |
| Sale | 2/1/2021 | (2,000) | $18.9900 |
| Sale | 2/4/2021 | (500) | $19.2000 |
| Sale | 2/5/2021 | (1,439) | $19.0000 |
| Sale | 2/5/2021 | (3,861) | $18.6201 |
| Sale | 2/11/2021 | (100) | $20.3200 |
| Sale | 2/11/2021 | (131) | $20.3200 |
| Sale | 2/16/2021 | (69) | $20.6500 |
| Sale | 2/16/2021 | (200) | $20.6000 |
| Sale | 2/16/2021 | (1,000) | $20.7000 |
| Sale | 2/16/2021 | (1,000) | $20.7000 |
| Sale | 2/19/2021 | (195) | $20.7900 |
| Sale | 6/30/2021 | (49) | $16.6900 |
| Sale | 6/30/2021 | (50) | $16.6200 |
| Sale | 6/30/2021 | (50) | $16.6300 |
| Sale | 6/30/2021 | (100) | $16.5100 |
| Sale | 6/30/2021 | (100) | $16.6600 |
| Sale | 6/30/2021 | (196) | $16.6500 |
| Sale | 6/30/2021 | (9,555) | $16.4500 |
| Sale | 9/2/2021 | (68) | $18.5901 |
| Sale | 9/2/2021 | (269) | $18.8200 |
| Sale | 9/2/2021 | (731) | $18.5400 |
| Sale | 9/2/2021 | (2,000) | $18.5900 |
| Sale | 9/9/2021 | (53) | $18.9900 |
| Sale | 9/9/2021 | (100) | $18.5820 |
| Sale | 9/9/2021 | (100) | $18.5840 |
| Sale | 9/9/2021 | (100) | $18.5860 |
| Sale | 9/9/2021 | (100) | $18.6300 |
| Sale | 9/9/2021 | (105) | $18.6000 |
| Sale | 9/9/2021 | (300) | $18.5900 |
| Sale | 9/9/2021 | (300) | $18.6200 |
| Sale | 9/9/2021 | (454) | $18.6100 |
| Sale | 9/9/2021 | (500) | $18.5800 |
| Sale | 9/9/2021 | (1,265) | $18.5701 |
| Sale | 9/9/2021 | (4,676) | $18.5700 |
| Sale | 9/23/2021 | (11) | $19.4900 |
| Sale | 9/24/2021 | (2,309) | $19.5100 |
| Sale | 9/27/2021 | (30) | $19.2800 |
| Sale | 9/27/2021 | (66) | $19.3000 |
| Sale | 9/27/2021 | (100) | $19.2525 |

**Spero Therapeutics, Inc. (SPRO)** **Kashif Memon**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Sale | 9/27/2021 | (400) | $19.2700 |
| Sale | 9/27/2021 | (480) | $19.2600 |
| Sale | 9/27/2021 | (924) | $19.2500 |
| Sale | 9/27/2021 | (1,000) | $19.2709 |
| Sale | 9/27/2021 | (1,000) | $19.2801 |
| Sale | 9/27/2021 | (1,000) | $19.3601 |
| Sale | 9/27/2021 | (1,000) | $19.4265 |
| Sale | 9/28/2021 | (1,000) | $19.5100 |
| Sale | 9/28/2021 | (1,000) | $19.5900 |
| Sale | 9/28/2021 | (1,000) | $19.6600 |
| Sale | 9/28/2021 | (2,000) | $19.4700 |
| Sale | 10/5/2021 | (500) | $18.7800 |

**CERTIFICATION PURSUANT**
**TO FEDERAL SECURITIES LAWS**

1. I, Richard S. Germond, make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

2. I have reviewed the initial complaint against Spero Therapeutics, Inc. ("Spero" or the "Company") and authorize the filing of an amended complaint on my behalf.

3. I did not purchase or acquire Spero securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.

4. I understand that the Court had the authority to select the most adequate lead plaintiff in this action and selected Kashif Memon. I am willing to serve as an additional representative party on behalf of a Class of investors who purchased or otherwise acquired Spero securities during the class period, as may be expanded, including providing testimony at deposition and trial, if necessary.

5. The attached sheet lists all of my transactions in Spero securities during the Class Period as specified in the amended complaint.

6. During the three-year period preceding the date on which this Certification is signed, I have not served or sought to serve as a representative party on behalf of a class under the federal securities laws.

7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the amended complaint, beyond my *pro rata* share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

8. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

**Executed** 12/1/2022
**(Date)**

DocuSigned by:
Richard S. Germond
0569E0A32D5F471...
**(Signature)**

**Richard S. Germond**

**Spero Therapeutics, Inc. (SPRO)** **Richard S. Germond**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Purchase | 12/24/2020 | 33 | $22.2650 |
| Purchase | 12/24/2020 | 46 | $21.7099 |
| Purchase | 1/20/2021 | 42 | $17.6000 |
| Purchase | 3/31/2021 | 75 | $14.1584 |
| Purchase | 4/8/2021 | 75 | $13.5000 |
| Purchase | 4/9/2021 | 40 | $13.0400 |
| Sale | 7/6/2021 | (170) | $15.2738 |
| Sale | 7/6/2021 | (170) | $15.2501 |
| Purchase | 7/9/2021 | 96 | $15.8000 |
| Purchase | 7/9/2021 | 4 | $15.2000 |
| Purchase | 8/4/2021 | 70 | $14.1000 |
| Purchase | 8/4/2021 | 10 | $13.9593 |
| Purchase | 8/6/2021 | 9 | $13.9555 |
| Purchase | 8/6/2021 | 11 | $13.9800 |
| Purchase | 8/31/2021 | 3 | $18.0232 |
| Purchase | 8/31/2021 | 52 | $18.4900 |
| Purchase | 8/31/2021 | 1 | $18.4000 |
| Purchase | 8/31/2021 | 4 | $18.4800 |
| Purchase | 8/31/2021 | 2 | $18.4200 |
| Purchase | 9/3/2021 | 38 | $18.0500 |
| Sale | 9/17/2021 | (35) | $19.5000 |
| Purchase | 10/28/2021 | 165 | $17.2700 |
| Purchase | 10/28/2021 | 7 | $17.3400 |
| Purchase | 10/29/2021 | 6 | $17.2500 |
| Purchase | 10/29/2021 | 10 | $17.2400 |
| Purchase | 11/1/2021 | 142 | $17.3800 |
| Purchase | 11/1/2021 | 5 | $17.3899 |
| Purchase | 11/1/2021 | 5 | $17.3600 |
| Purchase | 11/1/2021 | 1 | $17.4608 |
| Purchase | 11/10/2021 | 5 | $17.2500 |
| Purchase | 3/4/2022 | 109 | $8.7595 |
| Purchase | 3/4/2022 | 5 | $8.6000 |
| Purchase | 3/7/2022 | 16 | $8.3500 |
| Purchase | 3/8/2022 | 9 | $8.7500 |
| Purchase | 3/11/2022 | 25 | $8.6000 |
| Purchase | 3/16/2022 | 25 | $8.1000 |
| Purchase | 3/16/2022 | 2 | $7.7874 |
| Purchase | 3/31/2022 | 8 | $8.7100 |
| Purchase | 4/1/2022 | 19 | $7.0999 |
| Purchase | 4/28/2022 | 10 | $4.9495 |

**CERTIFICATION PURSUANT**
**TO FEDERAL SECURITIES LAWS**

1. I, Nabil Saad, make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

2. I have reviewed the initial complaint against Spero Therapeutics, Inc. ("Spero" or the "Company") and authorize the filing of an amended complaint on my behalf.

3. I did not purchase or acquire Spero securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.

4. I understand that the Court had the authority to select the most adequate lead plaintiff in this action and selected Kashif Memon. I am willing to serve as an additional representative party on behalf of a Class of investors who purchased or otherwise acquired Spero securities during the class period, as may be expanded, including providing testimony at deposition and trial, if necessary.

5. The attached sheet lists all of my transactions in Spero securities during the Class Period as specified in the amended complaint.

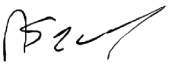
6. During the three-year period preceding the date on which this Certification is signed, I have served or sought to serve as a representative party on behalf of a class under the federal securities laws in the following action:

- *Feierstein v. Correvio Pharma. Corp.*, 1:19-cv-11361-VEC (S.D.N.Y.)

7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the amended complaint, beyond my *pro rata* share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

8. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

**Executed** 12/2/2022
**(Date)**



**(Signature)**

**Nabil Saad**

**Nabil Saad's Transactions in Spero Therapeutics, Inc. (SPRO)**

| Date | Transaction Type | Quantity | Unit Price |
|---|---|---|---|
| 3/25/2022 | Bought | 1,700 | $8.3699 |
| 3/25/2022 | Bought | 3,000 | $8.3399 |
| 4/7/2022 | Bought | 1,400 | $7.3100 |
| 4/7/2022 | Bought | 3,200 | $7.6600 |
| 4/7/2022 | Bought | 3,500 | $7.1000 |
| 4/7/2022 | Bought | 3,500 | $7.1000 |